Buginess	E	LABOR
EXHIBIT NO. 4		
DATE 3-21-	11	and the state of t
BILL NO HB408/	He	464,413275

HB 408 Reduced Statute of Limitations - shortens the time a Montanan has to file a malpractice claim to 2 years from the current 3 years that all other Montanans have. **HB 408** is another piece of **special legislation** that sets a shorter time than other injured Montanans in which those harmed by the negligence of agents of the healthcare industry may file suit to seek remedy for the harm they have suffered.

Section 3, the applicability date of the bill, would prevent Montanans from filing their claims if their injuries are more than 2 years old, but less than the current 3 years. HB 408 "applies to civil actions filed on or after [the effective date ...] (passage). Say this passes on April 15, 2011 – anyone with an injury that occurred from April 16, 2008 to April 15, 2009 would be precluded by this bill from filing a claim on April 16, 2011, even though they are within the current 3 year limit. Additionally, attorneys will need to start filing claims immediately for persons whose injuries occurred 24 months, 23 months, 22 months, etc, before the effective date – or risk a legal malpractice action.

In many other types of cases, especially vehicle cases, there is a professional, independent investigator (police, sheriff, MHP) who responds immediately to the scene and promptly documents the evidence. Insurance companies for both parties are put on notice and maintain a system to respond to the rights and liabilities of the parties. People injured in vehicle crashes need, and have, 3 years to determine their rights/liabilities, attempt settlement and, if necessary, start litigation.

In medical malpractice cases, the people who cause the injuries are usually the only ones who know all the facts about what happened. They are the only ones who make records. They decide what to put into the records, how to say it, and most importantly – what not to put into the records. There is almost never an investigation by an independent, objective professional. When there is, it is hidden from the patient, her family and the justice system by the peer review privilege. The doctors and hospitals control almost all of the information. If anything, the Montanans injured by preventable medical errors need more time than those injured by other types of negligence to attempt settlement and decide whether filing suit is necessary.

Medical cases are complicated, expensive and take a long time to adequately investigate. The issue of injury causation is often sufficiently complex that a good lawyer must investigate thoroughly before filing suit. This takes time, sometimes quite a bit of time because the injuries can be dynamic, changing in character and severity, and difficult to analyze. HB 408 may well increase, not decrease, the number of cases filed, with a rush to meet the 2 year deadline to preserve their rights.

How is this is going to "ensure that Montana residents receive quality health care?" It's going to ensure that those most badly injured by medical errors have even less time to heal before they have to sue. It's going to pressure people to bring claims before they know whether their injuries are permanent.

Do our **surrounding states** have less expensive, better medical care because they have a 2 year statute of limitations? We heard no evidence of that.

We did hear that North Dakota's cap on noneconomic damages is \$500,000, Idaho's is \$400,000, and Wyoming has no cap. Maybe to be more like our neighbors we should raise Montana's \$250,000 cap — the lowest in the country.

Whereas, the healthcare industry already has some 45 special statutes to protect it, as documented by the Montana Medical Association in it's *MMA Bulletin* of July/August 2009; and

Whereas, the Montana Medical Association describes the main special pieces of legislation as "qualitatively 'better' than measures in almost all states."; and

Whereas, the healthcare industry's solution to it's perceived problems are always to either reduce Montanan's access to the courts, or to reduce the damages that may be assessed for harms caused by the healthcare industry's failure to conform the care provided to the applicable professional standard of care; and

Whereas, Article II, Section 16 of the Montana Constitution provides that "Courts of justice shall be open to every person, and speedy remedy afforded for every injury of person, property or character.";

Whereas, **HB 408** is another piece of special legislation that sets a shorter time than other injured Montanans in which those harmed by the negligence of agents of the healthcare industry may file suit to seek remedy for the harm they have suffered; and

Whereas, **HB 408** will close the doors of the courts of justice to some Montanans in violation of their constitutional rights; and

Whereas, the Montana Medical Legal Panel reports that the number of claims filed against healthcare providers has been relatively stable, and the number of claims filed is less than those filed a decade ago; and

Whereas, **HB 408** will force Montanans to file more suits against all healthcare providers involved in an incident in order to preserve their rights than they do currently; and

Whereas, the conclusions of the whereas clauses of **HB 408** are self-serving, conclusory and unsupported by facts; and

Whereas, the healthcare industry's previous legislation to either reduce Montanan's access to the courts, or to reduce the damages that may be assessed for harms caused by the healthcare industry's failure to conform the care provided to the applicable professional standard of care NEVER SEEMS TO BE ENOUGH; and

Whereas, the one tried and true way to lower malpractice costs is to lower the number of Montanans harmed by agents of the healthcare industry.

BE IT RESOLVED THAT THE SENATE BUSINESS COMMITTEE OF THE 2011 MONTANA LEGISLATURE JUST SAY NO TO ANOTHER SPECIAL PIECE OF LEGISLATION FOR THE HEALTHCARE INDUSTRY AND **VOTE NO ON HB 408.**

Al Smith, Montana Trial Lawyers, 439-3124

HB 464 is another piece of special legislation that sets a higher evidentiary standard for some Montanans harmed by the negligence of a sub-set of the healthcare industry.

HB 464 creates a higher hurdle for Montanans who are harmed by the malpractice of pediatric and geriatric specialists - proving their case by clear and convincing evidence, unlike other malpractice victims and other injured Montanans that prove their case by a preponderance of the evidence.

HB 464 limits the rights of our most vulnerable citizens – the young and the elderly.

There were no facts to support the claim that taking away patient rights will aid in recruiting subspecialists. The closest we came to facts was that Dr. Rumans from the Billings Clinic testified in the House that the hardest doctors to recruit were internists, not geriatric specialists, and pediatric specialists were number 4.

Dr. Chavez, a pediatric specialist said in the House that increasing the number of pediatric specialists is dependent upon the state's population. BUT we just don't have enough kids to support more pediatric specialists.

Texas enacted draconian reforms promising more specialists in rural areas - they saw no increase in rural doctors, and an increase in people unable to receive any justice for the harm they and their families suffered.

There are many reasons why professionals choose to live where they do. Money, professional challenges, family, opportunities for spouses, education for their children, hospital facilities to name a few. We all love living in Montana, but we need to remember that this isn't the life for most people – most people live in metropolitan areas with all the trappings of civilization they have to offer.

I doubt that telling a pediatric and geriatric specialist that "In Montana, the evidentiary standard for you in malpractice cases is clear and convincing evidence" will be the deciding, let alone motivating factor to relocate to Montana.

Instead of us limiting the rights of Montanans harmed by preventable medical errors, maybe the health care industry should try recruiting by touting the 45 special statutes of protection that the Montana Medical Association in it's MMA Bulletin of July/August 2009 described as "qualitatively 'better' than measures in almost all states." Better yet the health care industry could use it's special protections to actually lower the number of preventable errors.

Recruiters can tout that there is no crisis with malpractice suits in Montana - the number of malpractice claims has decreased from 145 in 2000 to 122 in 2009. We have done more than most any other state to protect doctors and hospitals.

It's time to stand up and say no to limiting the rights of our most vulnerable. Let's reject the failed example of Texas, and protect equal rights for our kids and seniors.

Al Smith, Montana Trial Lawyers, 439-3124

Whereas, the healthcare industry already has some 45 special statutes to protect it,

as documented by the Montana Medical Association in it's MMA Bulletin of July/August 2009; and

Whereas, the Montana Medical Association describes the main special pieces of legislation as "qualitatively 'better' than measures in almost all states."; and

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Whereas, the healthcare industry's solution to it's perceived problems are always to either reduce Montanan's access to the courts, or to reduce the damages that may be assessed for harms caused by the healthcare industry's failure to conform the care provided to the applicable professional standard of care; and

Whereas, Article II, Section 16 of the Montana Constitution provides that "Courts of justice shall be open to every person, and speedy remedy afforded for every injury of person, property or character."; and

Whereas, the 7th Amendment to the U.S. Constitution protects our right to a trial by jury in civil matters; and

Whereas, these constitutional rights are the impetus of Section 27-1-701 of the Montana Code which provides that "each person is responsible not only for the results of the person's willful acts but also for an injury occasioned to another by the person's want of ordinary care or skill in the management of the person's property or person...."; and

Whereas, HB 464 is another piece of special legislation that sets a higher evidentiary standard for some Montanans harmed by the negligence of a sub-set of the healthcare industry; and Taking

Whereas, HB 464 closes the doors of the courts of justice to some Montanans in violation of their constitutional rights; and

Whereas, the conclusions of the whereas clauses of HB 464 are self-serving, conclusory and unsupported by facts, AND

Whereas, the healthcare industry's previous legislation to either reduce Montanan's access to the courts, or to reduce the damages that may be assessed for harms caused by the healthcare industry's failure to conform the care provided to the applicable professional standard of care NEVER SEEMS TO BE ENOUGH; and

Whereas, the one tried and true way to lower malpractice costs is to lower the number of Montanans harmed by agents of the healthcare industry.

BE IT RESOLVED THAT THE SENATE BUSINESS COMMITTEE OF THE 2011 MONTANA LEGISLATURE JUST SAY NO TO ANOTHER SPECIAL PIECE OF LEGISLATION FOR THE HEALTHCARE INDUSTRY AND VOTE NO ON HB 464.

Al Smith, Montana Trial Lawyers, 439-3124

HB 275 - VOTE NO TO AN INSURER WINDFALL

HB 275 reduces the amount that a medical malpractice insurer has to pay for a claim, simply because the patient harmed by malpractice dies, rather than lives. HB 275 simply means insurers get to keep more money.

The law did not change in 2002 - the 2002 case (*Payne*) simply said that 1987 changes to the law did not change the century old substantive law of Montana that deduction of consumption expenses are not allowed in survival actions - the same holding as a majority of the other states.

The Payne Court said the 1987 changes simply made clear that wrongful death and survival actions "must be combined in one legal action, and any element of damages may be recovered only once." 27-1-501

The Whereas statements are unsupported by facts, they are just conclusions. For example - Page 1, lines 21-22 - malpractice premiums are "a major contributor" to rising health care costs. FACT - the Congressional Budget Office found that total malpractice costs - insurance premiums paid, defense costs, and damages paid out to victims was less than 2% of total health care costs.

There was **NO TESTIMONY** that doctors are fleeing the state or refusing to come to the state simply because of malpractice insurance premium rates.

Proponents cited one case since 2002 where lost future earnings were awarded.

Without facts, there is no compelling state interest to justify denying medical malpractice victims the same rights as all other tort victims.

Malpractice Insurers Already Get Special Treatment They already have a damage cap of \$250,000, a special pre-court review panel, a special expert witness rule, a special statute of limitations, and special evidence rules. HB 275 is another special damage cap. Malpractice is not a "bad outcome" or a "mistake" - it is the failure to meet the standard of care for the profession.

Survival actions are different than wrongful death actions (see back).

Is it "fair" that the wrongdoer's insurance company pays less, simply because the victim dies, rather than lives?

When a person's life is taken because of the wrongful act of another, there are two civil legal actions- a wrongful death action and a survival action.

Wrongful death actions belong to the persons still living who have been injured by the death - usually spouses, parents and/or children. Damages include: loss of consortium; loss of comfort and society; and the reasonable value of the contributions in money that the decedent would reasonably have provided for support, education, training, and care. One MEASURE of support is lost future earnings. It is not simply that: (1) family members prove how much the deceased would have made, (2) the defense gets to deduct consumption expenses, and (3) the family gets the rest. The reality is that family members have to prove how much their dead family member would have contributed to them, taking into account how much the decedent would have consumed for his living expenses - necessities and personal spending. And then, the defense gets to argue that, had the person lived, they would have consumed more of those earnings, and therefore could not have contributed as much to the family members as they are asking for.

The survival action belongs to the decedent's estate and allows recovery for the injury to the deceased from the action causing death. The damages recoverable in the action are personal to the decedent and the estate's right of recovery is identical to the decedent's had he or she lived. In a survival action "the measure of damages is not lost support but rather lost earnings during the period the plaintiff would have lived if not for the injury. Speculating as to how the injured party may have spent those future earnings if not for defendant's tortuous conduct is a very different exercise than permitting a wrongful death plaintiff to prove damages for lost support by accounting for his or her supporter's other expenses." Payne (emphasis added).

The legal principle that a person's right to assert legal actions and defenses survives after his death has been the law in Montana since the late 1800's. It is a simple recognition that the wrongdoer should not be able to benefit economically, just because the victim dies. Survival actions are personal to the victim - the damage the victim suffered and what was taken away by the wrongful act, including lost future earnings.

The law did not change with the 2002 case (*Payne*), the Court only reiterated that Montana has followed, and continues to follow, the majority view in the country "that economic consumption should not factor into a loss of future earnings computation in survival actions."

While none of us has 100% of our earnings available to our estate when we die, we do get to choose how much of our earnings we spend, what we spend them on, who we spend them with - choices that are taken away from a malpractice victim when her life is cut short by medical malpractice.

It's time to decrease the occurrence of malpractice, instead of once again decreasing the amount of damages victims receive - victims who have proven malpractice has occurred and the damages that resulted. Vote NO to HB 275.

Prepared by Al Smith, MTLA, 439-3124

Montana "Tort Reform" Measures In Effect & Not In Effect Related To Medical Malpractice - 1977 Through 2009 ¹

Type Of Legislative Measures In Effect In Montana	
	In
Tort Reform Measure - Statute, Case Law Or Court Rule	Effect?
1. "Cap" On Non-Economic Damages - No Major Exceptions - Applies Per Claim	Yes
2. Statute of Limitations For Adults	Yes
3. Statute of Limitations For Minors Other Than Extending Limit Past Majority	Yes
4. Statute Of Repose - Time Beyond Which No Action Can Be Filed	Yes
5. Periodic Payment Of Future Damages	Yes
6. Collateral Source Offset - Duplicate Payment Of Damages	Yes
7. Comparative Negligence - Contribution - Joint And Several Liability	Yes
8. Mandatory Entry "Screening Panel" - Non-Binding Result Inadmissible At Trial	Yes
9. Mandatory Entry Mediation - Non-Binding Result Later Inadmissible	Yes
10. Voluntary Entry (Contractual), Binding Arbitration Contract After Incident	Yes
11. Voluntary Entry, Mediation After Event	Yes
12. No Statement of Damages In Complaint	Yes
13. Incident And Claims Data Reporting – To Board Of Medical Examiners	Yes
14. Report Of Incompetence Or Unprofessional Conduct - Immunity For Reporting	Yes
15. Peer Review Immunity	Yes
16. Punitive Damage Limits	Yes
17. Emotional/Mental Distress, Arising From Contract, No Recovery Of Damages	Yes
18. Vicarious Liability - Respondeat Superior ("The Thing Speaks For Itself") Yes	
19. Products Liability - Strict (Automatic) Liability (Responsibility For Damages)	Yes
20. Notification of Intent To Sue (Pre-requisite To Suit - Claim Filing With Panel)	Yes
21. Counter-Suit Availability, Especially For Bad Faith Or Frivolous Lawsuit	Yes
22. Costs Of Court To Prevailing Party - Valid Or Frivolous Lawsuits	Yes
23. Attorney Fees For Frivolous Lawsuits	Yes
24. Wrongful Death Actions - Combined With Survival Actions - Brought At Same	Yes
Time By Representative Of Estate - Duplicate Damages Eliminated	
25. Limit On Liability - Immunity For Officers, Directors & Volunteers Of Non- Profit Corporations	Yes
26. Limit On Liability - Directors Of Certain Corporations	Yes

Through 2011 Legislative Session. This inventory is current until Legislative changes in 2011 or after, if any. Of the available empirical scientific studies as to whether a specific tort reform measure has a downward or stabilizing effect on premiums, the rate of claims (frequency) or the payment on claims (severity), only the following meet that criteria, apart from measures that eliminate any liability and damages at all: Mandatory Pretrial Screening Panel; Modification Of Statutes Of Limitation; Ban On Naming Dollar Amounts In Initial Court "Complaint"; Limitations On Joint And Several Liability; Periodic Payment Of Future Damages; Offset Of Collateral Source Payment (Elimination Of Duplicate Payment Of Damages); Broad "Discovery" Of Medical Records For Claimants; Mandatory Risk Management Programs; Patient Compensation Funds; a "Cap" Or Other Limitations On Non-Economic Or Punitive Damages; Limits On Claimant Attorney "Contingency Fees". Except for Mandatory Risk Management Programs, A Patient Compensation Fund With A "Cap" On Maximum Liability, or Limits On Contingency Fees, each measure is present in Montana and each is qualitatively "better" than measures in almost all states. Any other measures may or may not have such an effect on the frequency-and severity of claims and even if it does, the insurance carrier must pass through those benefits for it to affect premiums. See, regarding scientific reports: Research Report 18, Effect Of Tort Reform Measures, Montana Medical Legal Panel, December 10, 2002. A fully footnoted version of this document is available, describing legislative histories, the impact of case law for Montana Supreme Court cases through mid-2005 and other legislative details, including statute sections and bill numbers.

Type Of Legislative Measures In Effect In Montana	
The second secon	i In
Tort Reform Measure - Statute, Case Law Or Court Rule (continued)	Effect?
27. Special Good Samaritan Law - Limits On Liability (No Ordinary Negligence) - Emergency Care For Assistance Rendered To Patient Of Direct-Entry Midwife By Licensed Physician, Nurse Or Hospital – Care Rendered With Or Without Compensation	Yes
28. Special Good Samaritan Law - Limits On Liability (No Ordinary Negligence) — Medical Practitioners, Including Licensed Physicians, And Dental Hygienists - Care Rendered Voluntarily & No Compensation — At Any Site — Patient Of Clinic, Patient Referred To Clinic Or Patient In A Community-Based Program To Provide Access To Health Care Services For Uninsured Persons	Yes
29. Special Good Samaritan Law - Limits On Liability (No Ordinary Negligence) - Governor Declared Authorized Disaster Or Emergency Medicine - For Assistance Rendered To Patient By "Health Care Professional" Where Normal Capacity Of Medical Resources Is Exceeded - Care Rendered With Or Without Compensation	Yes
30. General Good Samaritan Law – Limits On Liability (No Ordinary Negligence) – Any Person Including Licensed Physicians - Care Rendered Voluntarily & No Compensation - At The Scene Of An Accident Or Emergency	Yes
31. Advance Payment Of Damages, Fact And Amount, Not Admission & Not Admissible At Trial	Yes
32. Authorization For Physician-Owned Carriers	Yes
33. Committee Immunity For Peer Review - Confidentiality Of Data	Yes
54. Locality Rule - Standard Of Care	Yes
35. Limits On Pre-Judgment Interest	Yes
36. Inadmissibility In Court - Evidence Of Expressions Of Apology, Sympathy	Yes
37. No natural - Act or omission of other providers not within employment or control	Yes
36. Juint Underwriting Association - For Emergency Insurance Corrier	Yes
59. Incident And Claims Data Reporting - To Insurance Commissioner	Yes
40. Expert Witness Qualifications	Yes
41. Damage Limits - Loss Of Chance Doctrine Modification	Yes
42. Limit On Liability - "Captain Of The Ship" Doctrine Medification	Yes
45. No Liability - Acts Or Omissions Of "Ostensible" Agent	Yes
44. Panel Results Additionally Not Admissible In Bad Faith Action	Yes
45. Emergency Room Limits On Liability - Care To Patient Of Direct-Entry Midwife; Or Care Without Compensation As To Patient Of A Clinic, Patient Referred To A Clinic Or Patient In A Community-Based Program To Provide Access To Health Care Services For Uninsured Persons; Or Care Under Disaster Or Emergency Medicine	Yes

Type Of Legislative Measures NOT In Effect In Montana				
Tort Reform Measures - Not Enacted In Montana	In Effect?			
1. Patient Compensation Fund For Excess Insurance Coverage	No			
2. Cost Bond Before Filing In District Court	No			
3. Certificate Of Merit By Physician, Prior To Lawsuit, Good Cause To Sue Exists	No			
4. "No Fault" Administration Mechanism For Resolution Of Dispute 5. Mandatory Entry, Binding Arbitration	No			
6. Attorney Fees To Prevailing Party	No			
	No No			

Type Of Legislative Measures NOT In Effect In Montana				
Tort Reform Measures - Not Enacted In Montana (continued)	In Effect?			
Dallages - Emotional Distress Arising Franch	No			
Timount Of Contingency Kees (Reverse Sliding Seels O. O.)	No			
Malpractice Prior To Event (Medical Malpractice)	No			
10. Mandatory Risk Prevention Programs	No			
11. Limits On Expert Witness Fees	No			
12. Deduction Of Decedent's Future Personal Consumption Expenses From Award Of Future Lost Earnings In Survival Actions	No			

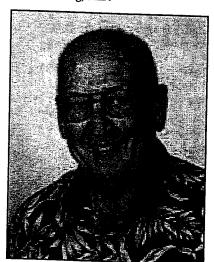
[Modified 7/16/2009]

served. Can people in rural areas expect that from a national system? Has the Indian Health Service been able to provide that to its clientele? Has the VA?

How can an increasingly specialized profession based in urban areas be made to function in increasingly isolated, rural areas where health needs are often generalized? Dr. Whiting's excellent and timely book offers some useful insights and suggestions to these questions.

I enjoyed this book and gave it five stars. It's well-written, insightful and it will appeal not only to those who know Dr. Whiting, his family and the area he served, but to medical professionals, social historians studying the flight from rural areas to urban areas, and Americans everywhere who are contemplating the great debate over the creation of a national health system for the US.

--Review by John M. Lane --Robert Whiting, M.D.



FROM WHERE I SIT...

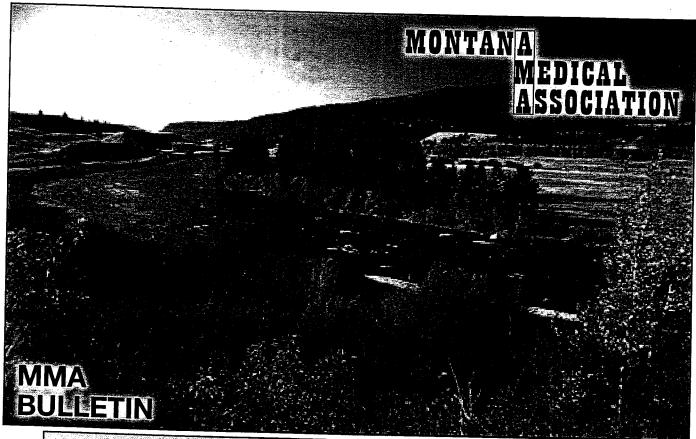
There may never have been a time when direct contact between physicians and their Washington D.C. representatives was more important. The push for a "Health Plan" is marching on in at least three fronts and the opportunities to affect the end results are gradually coming to an end. Whether or not the legislative and executive branches can get together is one question. Before that comes up, the legislative branches will have to try to agree on one plan which will require some compromises between the House and Senate plans. The driver of the bus on the Senate side is Senator Baucus.

Our input should be centered on what is best for patients. There are daily editorials and articles in the local and national news papers on the subject. Many are quite thoughtful. The American Medical Association has attempted to put their suggestions into the mix. Will anyone listen to organized medicine? That is a good question. What is being presented by our leadership are principles passed by the AMA House of Delegates. No matter who is speaking for the AMA, it will have less of an impact on our own senators and representative than communications in any direct form from Montana physicians. Who speaks is just as important as what is said. The MMA office has passed on the information from the AMA on the AMA position and the specific comments from the AMA on the House bill. If you do not have them or did not receive them, I suggest you contact the AMA office. They have been sent to the members by e-mail and I fully realize that many physicians do not check e-mail regularly if at all. One of the documents is very specific in a question and answer format on the House bill explaining as well as clearly detailing the reasons behind the AMA position.

The adage "Politics is personal" is absolutely true. We have an opportunity to affect the care of patients for generations to come. We have all had experiences where we did not speak up and wish we had. Many believe that they cannot have any influence on what happens in Washington. My own personal experience is that we can have significant influence. We should all act as if our representatives really do work for and are on our payrolls. All of us get reminded of this every March when the income tax issue is clearly brought to our attention. No profession knows medicine as we do. No one has the same patient relationship that we do. A letter, e-mail or phone call now may be the information one of our representatives uses to help make any legislation passed more appropriate for patients.

A health care plan that would encourage physicians to avoid caring for the sickest patients would be a tragedy. Rewards for a computer based system that pits physicians against one another for the best results using billing data can produce such a tragedy. We have to be sure that the decision makers in Washington understand this. A de-identified actual story about a patient is the best thing we can do to help our representatives understand real and potential effects from bad legislation. It is perfectly correct to make contacts more than once. After about the third time the Washington staffs and representatives will "know you." Have a good summer and please make your D.C. contacts now.

--John W. McMahon, Sr., M.D., Medical Director, Mountain Pacific Quality Health Foundation

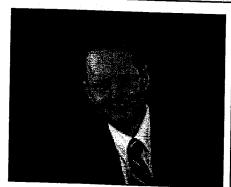


"A fly fisherman's 'dream stream,' the Madison River near Ennis" Photographer: Rick and Susie Graetz, Northern Rockies Publishing, Helena

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Kirk L. Stoner, M.D., President

PRESIDENT'S MESSAGE

At the recent AMA annual meeting a number of issues important to physicians were covered. The overriding issue was health system reform. It was apparent that all physicians recognize that reform is going to occur. It is important that we, as the experts in patient care, let our legislators know our opinions. Our AMA President Nancy Nielsen, spoke of building bridges during this seminal time. It is important to

have positive recommendations and suggestions to make. It was painfully obvious that many physicians are extremely distrustful of any promises that the government may make, rightfully so. However, we cannot let this negative feeling undermine the positive benefits that may come from health care reform.

The overwhelming concern of physicians was that the physician-patient relationship is being eroded by various administrative decisions at numerous levels including governments, insurance companies, and hospitals. Additionally, there is increasing concern about the financial viability of many physician practices because of low reimbursements and increasing overhead. The AMA is at the table and making these concerns known to the Congress. They are a strong advocate for the patient-physician relationship.

President Obama's speech before the AMA House of Delegates was a political speech but did give a little insight into what the

At-a-Glance

Nominees for MMA Officer Elections

Program of MMA's 131st Annual Meeting

Montana Recovery Audit Contractor (RAC) Seminar

> More Enforcement of Medicare Claims

Montana Tort Reform Measures 1977-2009 10 - 12

Physicians: Please provide your current email address for your office.



MONTANA MEDICAL LEGAL PANEL

2009 ANNUAL REPORT As Of March 12, 2010

MONTANA MEDICAL MALPRACTICE CLAIMS; HEARINGS: LAWSUITS AND JURY TRIALS

MONTANA MEDICAL LEGAL PANEL

G. Brian Zins, Director Kathy Stepp, Assistant Director 2021 11th Avenue, Helena, Montana 59601

MONTANAMEDICALLEGALPANEL

NUMBER AND RATE OF FILED MEDICAL MALPRACTICE CLAIMS

ANNUAL DATA

		ANNUAL DATA	
Panel Claim	Number (0) Classis.		Number Of Claums As A Ler centage Of Montana Health Ca
Filing Year	Miled AcTine Panel	Brovides	Providers
1980	31	1,219	2.5%
1981	37	1,276	2.9%
1982	78	1,250	6.2%
1983	91	1,316	6.9%
1984	104	1,260	8.3%
1985	80	1,266	6.3%
1986	124	1,226	10.1%
1987	97	1,226	7.9%
1988	101	1,795	5.6%
1989	110	1,806	6.1%
1990	102	1,808	5.6%
1991	85	1,765	4.8%
1992	101	1,947	5.2%
1993	121	1,983	6.1%
1994	121	2,073	5.8%
1995	150	2,122	7.1%
1996	139	2,143	6.5%
1997	143	2,148	6.7%
1998	146	2,189	6.7%
1999	149	2,230	6.7%
2000	145	2,272	6.4%
2001	139	2,416	5.8%
2002	149	2,414	6.2%
2003	170	2,547	6.7%
2004	153	2,558	6.0%
2005	175	2,623	6.7%
2006	130	2,618	5.0%
2007	136	2,738	5.0%
2008	110	2,783	4.0%
2009	122	2,905	4.2%
Total 2	\$1.5% (Parties 12)	, **	

Claims filed in the early years of the Panel were only as to those claims where the date of incident was on or after April 17, 1977, hence a period of approximately six years was required – until 1982 – before the "true" rate of Claims could be observed.

Committee Set relain

PATIENT SAFETY SERIES

Effect of a comprehensive obstetric patient safety program on compensation payments and sentinel events

Amos Grunebaum, MD; Frank Chervenak, MD; Daniel Skupski, MD

I mproving patient safety has become L an important goal for hospitals, physicians, patients, and insurers. Implementing patient safety measures and promoting an organized culture of safety, including the use of highly specialized protocols, has been shown to decrease adverse outcomes;2-5 however, it is less clear whether decreasing adverse outcomes also reduces compensation payments and sentinel events.

Our objective is to describe comprehensive changes to our obstetric patient safety program and to report their impact on actual spent compensation payments (sum of indemnity and expenses paid) and sentinel events.

Materials and Methods

New York Presbyterian Hospital-Weill Cornell Medical Center is a tertiary academic referral center with a level 3 neonatal intensive care unit and serves as a New York State regional perinatal center. The labor and delivery unit performs about 5200 deliveries per year of which voluntary attending physicians manage approximately 25%, and 75% are managed by full-time faculty.

The New York Weill Cornell Investigation Research Board approved this report as exempt research.

Patient safety program

In 2002, we began to implement in a step-wise fashion a comprehensive and

From the Department of Obstetrics and Gynecology, New York Weill Cornell Medical Center, New York, NY.

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doi: 10.1016/j.ajog.2010.11.009

Our objective was to describe a comprehensive obstetric patient safety program and its effect on reducing compensation payments and sentinel adverse events. From 2003 to 2009, we implemented a comprehensive obstetric patient safety program at our institution with multiple integrated components. To evaluate its effect on compensation payments and sentinel events, we gathered data on compensation payments and sentinel events retrospectively from 2003, when the program was initiated, through 2009. Average yearly compensation payments decreased from \$27,591,610 between 2003-2006 to \$2,550,136 between 2007-2009, sentinel events decreased from 5 in 2000 to none in 2008 and 2009. Instituting a comprehensive obstetric patient safety program decreased compensation payments and sentinel events resulting in immediate and significant savings.

Key words: compensation payments, medical liability, obstetric adverse outcomes, patient safety, sentinel events

ongoing patient safety program. The date of implementation is included for each step.

Consultant Review (2002)

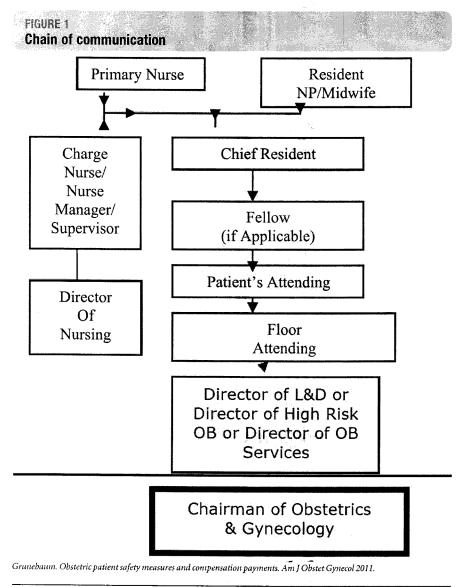
In 2002, as part of an obstetric initiative by our insurance carrier (MCIC Vermont, Inc, Burlington, VT), 2 independent consultants reviewed our department and assessed our institution's obstetric service. This review resulted in specific recommendations and provided a general outline for making changes and improvements in patient safety. Building on these findings, we implemented a comprehensive obstetric patient safety program.

Labor and delivery team training (2003)

Poor communication is among the most cited reasons for malpractice suits,6 whereas improved nurse-physician communication can make labor and delivery safer.7 Consequently, the Institute of Medicine recommended interdisciplinary team training programs for providers to incorporate proven methods of team training as a way to improve efforts

and to empower every team member to speak up and intervene if an unsafe situation may be occurring.8 Crew Resource Management (CRM) can potentially decrease medical malpractice litigation, mostly by improving communication,9 but studies have been less clear about its effect on adverse outcomes.¹⁰

In 2003, several of our labor and delivery staff members including nurses, obstetricians, and anesthesiologists attended a "train the trainer" team-training course. Subsequently, all staff working on labor and delivery including clerical staff, nurses, attending obstetricians, neonatologists, anesthesiologists, and residents successfully attended a 4-hour team training session and team principles were introduced on labor and delivery. Since then, all new staff has been required to attend labor and delivery team training sessions. The CRM program is performed regularly every 2-3 months. New staff, including nurses, attending, residents, and clerical staff, are scheduled to undertake CRM at the next available time. Attending physicians are instructed that credentialing/privileges will not be



granted or renewed if CRM is not completed and nursing staff and residents are informed that they must take the CRM program within a year after employment begins.

Electronic medical record charting (2003)

Good medical record charting can help defend professional liability cases and may persuade potential plaintiffs to forego filing a suit¹¹ and electronic health records on labor and delivery are less likely to miss key clinical information.¹² To facilitate communication and to improve patient safety, we were among the first departments in our institution to require electronic medical

record charting with Eclipsys XA (Eclipsys Corporation, Boca Raton, FL) for all patients on labor and delivery. OB Tracevue (Phillips, Andover, MA) is used for electronic fetal monitoring (EFM). All documentation occurs in these electronic formats. Paper documentation is not allowed, except when the electronic format is temporarily incapacitated.

Chain of communication for labor and delivery (2003)

Communication on labor and delivery is crucial to ensure patient safety and to provide the best care for patients and prevent errors, 13 but there are times when physician's orders and actions

need to be questioned. We believed that the most effective way for staff on the labor and delivery unit to voice their concerns is to establish and promote chainof-communication policies. In 2004, a new chief of labor and delivery was appointed and a clear chain of communication was established and supported by the departmental chairman (Figure 1). The chain of communication includes involvement of all staff beginning at the nurse and junior resident level, then up to the chief resident, the inhouse attending, the maternal-fetal medicine specialist on call, and finally the director of labor and delivery and the chairman of the department. All staff are being empowered to use the chain of communication frequently and around the clock to ensure a quick resolution to unresolved and urgent issues.

Dedicated gynecology attending on call (2004)

A gynecology attending on call schedule was established separately from the obstetric coverage. Before this change, the labor and delivery attending covered both the obstetric and gynecology services and there had been occasions when there were concurrent emergency gynecologic and obstetric cases. This situation prevented the attending from sufficiently covering both services. The added gynecology coverage allowed the labor and delivery attending to cover the labor floor exclusively.

Limitation of misoprostol to induction of labor or cervical ripening for a nonviable fetus (2004)

Misoprostol is not US Federal Drug Administration (FDA) approved for use during labor. There is evidence that misoprostol is not effective, ¹⁴ and its use is associated with an increase in hyperstimulation/tachysystole. ¹⁵

Misoprostol has never been used at the medical center for a live fetus. After the warning from the Searle company discouraging its use in the year 2000, there was no incentive to begin using this medication at our institution, and our concern about potential adverse outcomes led us to conclude that misoprostol use

Stanuar	dized protocol for induction or augmentation with oxytocin
Item	Protocol
a.	Only a premixed oxytocin solution is used
b.	The oxytocin infusion is limited to intravenous route via an infusion pump
C.	A buretrol infusion is used with a "smart pump" (a pump that comes with error reduction system and drug library capabilities)
d.	The infusion is piggybacked into the port most proximal to patient
e.	A written attending order (electronic template) is required before the start of oxytocin
f.	Before the start of oxytocin an attending must document the plan of care including indication, fetal presentation and station, cervical status, estimated fetal weight, pelvic adequacy, and fetal heart rate assessment.
g.	An attending must be available on the same floor as labor and delivery floor at all times while the patient is on oxytocin
h.	Before initiation of oxytocin a reassuring fetal heart rate must be present for a minimum of 20 minutes
i.	The oxytocin concentration is a premixed solution of 30 U per 500 mL. No individual mixing of solutions is permitted onsite.
j.	The oxytocin infusion begins at 1 mU per minute.
k.	The infusion is increased by 1 mU per minute no more frequently than every 15 minutes
l.	An attending must evaluate, document, and determine the plan of care if the oxytocin dosage reaches 20 mU per minute
m.	The maximum oxytocin dosage cannot exceed 40 mU per minute
n.	If the oxytocin infusion was discontinued for 20 minutes or less, it may be restarted at a lower rate than before discontinuation. It it was stopped for greater than 20 minutes then it should be restarted at 1 mU per minute
0.	Only a nurse can titrate oxytocin. The nurse can stop or titrate the oxytocin infusion if indicated. The doctor must be notified of this.
p.	The oxytocin infusion must be stopped or titrated for any of the following: uterine hyperstimulation/tachysystole (contractions less than 2 minutes in frequency and/or lasting longer than 90 seconds and/or more than 5 contractions in any 10 minute period); elevated uterine resting tone; nonreassuring fetal heart rate tracing; presumed uterine rupture; water intoxication
q.	The attending physician must be notified of any hyperstimulation/tachystole, abnormal fetal heart rate changes and/or stoppage or down titration of oxytocin.
r.	Terbutaline may be given if stopping oxytocin does not lead to a normalization of fetal heart rate changes in the presence of hyperstimulation
s.	Oxytocin should be discontinued as soon as a cesarean delivery is planned

should be limited to induction of labor and cervical ripening only in the nonviable fetus.

Standardized oxytocin labor induction and stimulation protocol (2005)

A standardized protocol enables the staff to become facile in handling the myriad of problems that occur on any busy unit, quickly and efficiently. ¹⁶ In 2005, we implemented a standardized low-dose oxytocin labor induction and stimulation policy (Table 1) and a standardized order template was designed in the hospital's electronic ordering system (Eclipsys, Atlanta, GA). No other method of using intrapartum oxytocin was permitted. Highlights of this protocol included

a premixed oxytocin solution, a required written attending order and note before starting the oxytocin infusion, a standardized starting dosage and increases, and a "smart pump" (a pump that comes with an error reduction system and drug library capabilities). The protocol paid special attention to tachysystole and fetal heart rate concerns. If there was tachysytole, or there were concerns about the fetal heart rate, the oxytocin infusion had to be decreased or stopped.

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Premixed and safety color-coded labeled magnesium sulfate and oxytocin solutions (2005)

Magnesium sulfate is among the most dangerous solutions used on labor and

delivery.¹⁷ More recently, in addition to seizure prophylaxis and tocolysis, prevention of cerebral palsy was added as a potential indication for giving magnesium sulfate on labor and delivery.^{18,19} To improve the safe use of magnesium sulfate, we implemented several changes, including the use of premixed magnesium sulfate and oxytocin solutions, color coded magnesium sulfate and oxytocin containers and intravenous lines, as well as using both with "smart pumps."

Electronic medical record templates for shoulder dystocia and operative deliveries (2005)

Both shoulder dystocia and operative deliveries are associated with an increase in

TABLE 2 Shoulder dystocia documentation template Shoulder dystocia note Head delivery (Spont/Forc/Vac): Time head delivered (min/sec): Time body delivered (min/sec): Second stage (min): Anterior shoulder (right/left): Initial traction: gentle attempt at traction, assisted by maternal expulsive forces Oxytocin stopped: yes or no Terbutaline given: yes or no Any/all maneuvers that apply and the order in which they were utilized. McRoberts maneuver and by whom: Suprapubic pressure and by whom: Episiotomy (and by whom): Rubin's maneuver and by whom: Woods maneuver and by whom: Gaskin maneuver (all fours): Posterior arm release and by whom: Other (maneuvers list): 3 **4** No Fundal pressure after the head delivered The arm under the symphysis at the point the head was delivered was: right OR left Primary Care Provider(s) present: Registered Nurse(s) present: Pediatrician(s) present: Others present: Full disclosure given to patient: Yes/No 163 .. Grunebaum. Obstetric patient safety measures and compensation payments. Am J Obstet Gynecol 2011.

neonatal and maternal injury and consequently litigation.²⁰ Making the correct diagnosis, performing the correct maneuvers, time management, prevention of traction, and documenting management and maneuvers are therefore essential.²¹ We designed and implemented required templates and electronic medical charting tools for several clinical situations, including shoulder dystocia and operative delivery (Table 2).

Early identification of potential obstetric professional liability cases (2005)

Our medicolegal department met with our department and decided that early identification of adverse obstetric outcomes and potential professional liability cases and expedited reviews would be implemented. If a clear medical error was identified, we planned to approach the patient with the goal of an early settlement. Since the implementation of this program, 1 adverse outcome (an early neonatal death) was identified and quickly settled.

Obstetric patient safety nurse (2005)

As part of our patient safety efforts, our insurance carrier (MCIC Vermont, Inc) funded an obstetric patient safety nurse. The patient safety nurse is employed fultime by the hospital and is involved in staff education, team training, implementation of protocol changes on labor and delivery, obstetric emergency drills, and collection of data.

Electronic online communication whiteboard (2006)

For decades, the labor whiteboard has been the center of communications on many labor and delivery units. It usually serves as a hub for situational awareness to make all staff aware of events on labor and delivery. However, the traditional dry erasable whiteboard has many disadvantages, including limited visibility, limited access, small size, no interactivity, and inflexibility. We programmed and implemented our own proprietary online electronic whiteboard (http:// www.LDTrack.com), a secure passwordprotected and IP address-controlled site available through any internet browser that has many interactive features, including color-coded warning labels and automatic mathematically supported updates.22

Recruitment of physician's assistants for labor and delivery (2006)

Newly instituted resident work hours limit the extent of resident involvement and night calls in the hospital including the labor and delivery unit. Three new obstetric physician assistants were recruited to amplify the staff and help with the workload. The physicians' assistants are assigned to labor and delivery triage and as assistants for cesarean deliveries and provide continuity and stability on the labor and delivery floor.

Electronic fetal monitor interpretation certification (2006)

Effective communication is essential when discussing and interpreting fetal heart rate and uterine activity and it requires a mutual understanding of terminology. We required that all staff involved in interpreting electronic fetal monitoring, including attendings, residents, physician assistants, and nurses, become certified in electronic fetal monitoring by National Certification Corporation (NCC), a not-for-profit organization that provides a national credentialing program for nurses, physicians, and other licensed health care professionals. In addition, all staff are required to use the National Institute of Child and Human Development

(NICHD) standardized language for fetal heart rate interpretation²³ and templates for documenting fetal heart rates based on the NICHD language were added in the electronic charting tools.

Electronic antepartum medical records (2006)

We implemented uniform antepartum medical record charting (Epic Systems Corporation) for all full-time faculty and staff patients (about 75% of all deliveries). The availability of electronic antepartum charts on a 24-hour/7 day a week basis improves availability of data, such as laboratory results and helps in improving communication among the staff.

Routine thromboembolism prophylaxis for all cesarean deliveries (2006)

Pulmonary thromboembolism is among the leading causes of maternal deaths in the United States, and most events of venous thromboembolism can be reduced with either medical or mechanical thromboprophylaxis,24,25 and it has been suggested that a systematic reduction in maternal death rate in the United States can be expected if all women undergoing cesarean delivery receive thromboembolism prophylaxis. 5 Therefore, in addition to using pharmacologic anticoagulation prophylaxis for high-risk patients, we also implemented the routine use of intermittent lower extremity pneumatic compression devices for all cesarean deliveries.

Obstetric emergency drills (2006)

The Joint Commission recommends that obstetric departments consider periodically conducting clinical drills to help staff prepare for shoulder dystocia, conduct debriefings to evaluate team performance, and identify areas for improvement.13 Such drills appear to improve recognition and management of shoulder dystocia and can improve physician's communication skills as well as reduce traction forces.^{26,27} Drills were instituted over time for maternal cardiac arrest, shoulder dystocia, emergency cesarean section, and maternal hemorrhage. Obstetricians, anesthesiologists, neonatologists, nurses, residents, fellows, and physician assistants participate in these drills. The shoulder dystocia and maternal hemorrhage drills are performed with a maternal and fetal manikin and in small groups of 6-8 individuals so each can obtain practice in performing the necessary fetal manipulations.

The main objectives of the shoulder dystocia drill are to diagnose shoulder dystocia, prevent injury by performing the correct maneuvers, time management, prevention of traction, and teach proper documentation.

Recruitment of a laborist (2007)

Inhouse oncall attending coverage is provided on a 24-hour basis by one of the full-time faculty attendings that have obstetric privileges. To address lifestyle and patient safety concerns, Weinstein recommended a practice of having hospitalists and laborists,²⁸ Clark recommended a reassessment of group obstetric practice to improve patient safety,²⁹ and a survey showed that laborists can have a high career satisfaction. 30 In 2006, we hired a laborist to provide inhouse coverage for the labor and delivery floor for nights and weekends and therefore reduce inhouse oncall responsibilities of other physicians.

Oxytocin initiation checklist (2009)

We implemented a checklist with the most important elements of the standardized oxytocin policy. Completion of the checklist is required by nurses before initiation of oxytocin for induction or stimulation of labor.

Postpartum hemorrhage kit (2009)

We made available a single hemorrhage kit that includes the 4 most important drugs used for postpartum hemorrhage (oxytocin [Pitocin; King Pharmaceuticals, Bristol, TN], misoprostol [Methergine; Novartis Pharmaceuticals, Basel, Switzerland, Cytotec; Bristol-Myers Squibb, Skillman, NJ], carboprost [Hemabate; Pfizer, New York, NY]). ...

Internet based required reading assignments and testing (2009)

We created an inhouse internet-based password protected reading and testing program (http://www.InPrep.com) for protocols and other publications related to labor and delivery safety. All attendings and residents have been required to regularly read assigned literature and pass a multiple choice test related to the reading material.

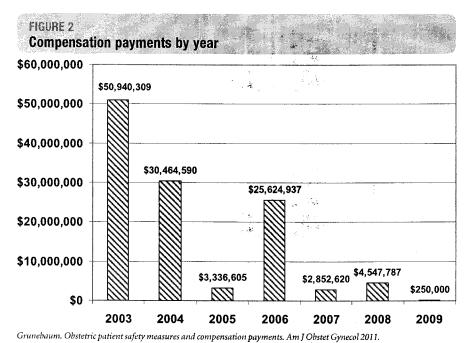
Compensation payments and sentinel events

We performed a retrospective review of obstetric compensation payments from 2003 to 2009 collected by the MCIC. Obstetric compensation payments were defined as all actual payments made as a sum of indemnity paid plus medicolegal expenses paid for by the hospital for defending the case. In New York City, most professional liability suits are initiated within 2-3 years after delivery, and they are often not settled until many years later. Therefore, in addition to actual compensation payments, we also assessed new and ongoing significant professional liability suits (expected at \$1,000,000 and above) and potential future professional liability suits. Data on sentinel events at our institution were evaluated from 2000 to 2009 by analyzing data obtained from a sentinel event adverse outcome database that is prospectively recorded by the hospital's quality assurance committee. Sentinel events are determined by the Medical Center according to Joint Commission standards. The Joint Commission defines a sentinel event as "... an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof ..." (http://www. jointcommission.org/SentinelEvents/). At our institution, sentinel events included maternal deaths, and serious newborn injuries, including birth asphyxia and hypoxic ischemic encephalopathy.

Results

Compensation payments

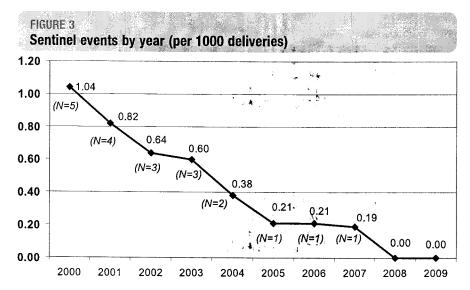
Figure 2 shows the yearly obstetric compensation payment totals paid out from 2003 to 2009. The 2009 compensation payment total constituted a 99.1% drop from the average 2003-2006 payments (from \$27,591,610 to \$250,000). The average yearly compensation payment in the 3 years from 2007 to 2009 was



\$2,550,136 as compared with an average of \$27,591,610 in the previous 4 years (2003-2006), a yearly saving of \$25,041,475 (total: \$75,124,424) during the last 3 years.

The compensation payments between 2003 and 2008 included delivery dates before 2003. We also assessed potential future and pending professional liability suits through the early identification program. In 2006, we had 1 adverse outcome case that was identified through

our program for the early identification of potential professional liability cases, and the case was settled expeditiously. In 2008 and 2009, for the first time in this decade, there was no professional liability suit initiated involving a possibly brain-damaged infant. In addition, there is currently only 1 active professional liability suit exceeding a \$1 million estimated loss for an obstetric case from 2005 onward. One of the 2 other cur-



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rently pending "baby damage" suits involves deliveries before 2003.

Table 3 shows the average time it takes from the event to payment. There is an average of 6.9 years (range, 0.6-17.1 years) between the event and the payment. On average, it takes 3.2 years (range, 0-10 years) between the event and the claim and another 3.7 years (range, 0.3-10.4 years) between the claim and the payment. Of all claims, 65% (26/40) were made within 3 years after the event and 49% of payments (20/ 41) were made within 6 years after the event.

Sentinel events and adverse outcomes

Figure 3 shows the yearly rate of sentinel events per 1000 deliveries. There was a steady decline of sentinel events over the years of the study, from 1.04 sentinel events per 1000 deliveries in the year 2000, to no sentinel events in both 2008 and 2009. For the last 6 years, there has been no maternal death on labor and delivery (we had 1 postpartum maternal death 10 days after discharge from a cerebrovascular accident) and there has been no permanent Erb's palsy since we began shoulder dystocia drills in 2008. Since 2007 there was only 1 infant born of a total of 15,932 deliveries with the diagnosis of hypoxic ischemic encephalopathy (HIE) for an incidence of 0.6 HIE of 10,000 deliveries. Subsequently, that infant had no moderate or severe neurodevelopment impairments. In 2009 there was no infant born with HIE.

The definition of HIE included a severely depressed newborn with need for resuscitation in the delivery room, evidence of severe acidemia at birth based on cord blood gas values and early abnormal findings on neurologic examination and/or abnormal assessment of cerebral function.32

Comment

In 1999, the Institute of Medicine published a report challenging the prevailing wisdom that all was well with the American health care system.8 This report called for a sweeping overhaul and stated that "higher level of care cannot be achieved by further stressing current systems of care. The current care systems cannot do the job. Trying harder will not work. Changing systems of care will." There also have been increasing concerns about the rise in malpractice costs and its effect of availability of health care.31

After an external review of our obstetric service, we undertook comprehensive system changes beginning in 2003, to improve patient safety on our service. Among these patient safety changes were significant eliminations in practice variations as well as significant improvements in communication methods between staff. The main goal of these changes was to improve patient safety and decrease adverse outcomes. We did not expect a rapid and significant effect on compensation payments.

Our results show that implementing a comprehensive obstetric patient safety program not only decreases severe adverse outcomes but can also have an immediate impact on compensation payments. Beginning with the fourth year of the program, compensation payments began to drop significantly. Yearly payments for the most recent 3 years (2007-2009) averaged \$2,550,136 as compared with average yearly payments of \$27,591,610 for the preceding 4 years (2003-2006). The \$25,041,475 yearly savings in compensation payments for the last 3 years alone dwarf the incremental cost of the patient safety program and are well above those reported by Simpson et al.³² In our opinion the documented success of our patient safety improvement program in decreasing compensation payments for the past years understates the true long-term impact of the program on patient safety, as we expect significant savings to continue into the future.

Our neonatal intensive care unit is a center for "cool cap" treatments (treatment of infants with neonatal encephalopathy with hypothermia helmets), and it regularly treats infants with HIE.³³ Of the more than 50 infants with HIE who were treated in this program over the last 3 years, only 1 among our own 15,932 deliveries came from our institution (the only 2007 sentinel event). Our observed departmental incidence of 0.6 HIE of 10,000 deliveries in the last 3 years is well

TABLE 3 Yearly compensation payments and event-to-payment time

Year	Payments	Event-to-payment average (range), y
2003	\$50,940,309	5.9 (1.1–10.3)
2004	\$30,464,590	10.5 (3.9–17.1)
2005	\$3,336,605	5.5 (1.2–9.5)
2006	\$25,624,937	8.2 (4.1–13.2)
2007	\$2,852,620	8.1 (5.0–12.0)
2008	\$4,547,787	4.7 (0.6–14.4)
2009	\$250,000	0.8
2003-2009	\$117,991,848	6.9 (0.6–17.1)
	ient safety measures and compensation pay	

below the reported 25 of 10,000 deliveries.34 On follow-up, this infant had no moderate or severe neurodevelopment impairments and hence for the last 3 years there are presently no known HIE brain damaged infants "in the pipeline." As the amount of compensation payments for an infant with neurodevelopment impairments can be well in excess of \$10 million in New York City, the prevention of each and every 1 of these cases is crucial to minimize such payments.

The Institute for Safe Medication Practices (ISMP) has added oxytocin to its list of high alert medications.³⁵ The use of oxytocin during labor has been found to be associated with malpractice claims.³⁶ Using oxytocin during labor may have a negative impact on the probability of successfully defending a professional liability case, and its misuse, especially its association with hyperstimulation, has been alleged to be responsible for many if not most of the adverse outcomes and professional liability litigation involving abnormal labor. 37-40

The best defense against legal challenges involving the misuse of oxytocin is to use the drug judiciously and in accord with institutional policies. 41 However, despite reports that standardized and uniform practice patterns are known to have better outcomes than greater practice variations, medical practice continues to be characterized by wide variations that have little basis in clinical science.16 This is especially true for oxytocin usage, which has many persistent variations even within the same institution. 42 Clark et al 41 concluded that a physiologically sound and evidencebased approach to oxytocin use is possible and explained that it may be difficult to effect change in practice when physicians so often see no untoward effects of excessive uterine activity.

It has been suggested that implementing a uniform oxytocin policy and using an oxytocin checklist may improve perinatal outcomes. 43-45 We also found that implementing a uniform oxytocin protocol and checklist helped our staff make better use of oxytocin and allowed nurses to focus on better patient care instead of following protocols that varied from physician to physician. Implementing a uniform oxytocin protocol likely contributed to our improved patient safety and prevention of adverse outcomes. Our experience supports the recommendation that: "... Malpractice loss is best avoided by reduction in adverse outcomes and the development of unambiguous practice guidelines."5

Many pregnant women are given misoprostol "off-label" for cervical ripening and labor induction even though this medication is not approved for use in labor and is associated with an increase in uterine hyperstimulation and resultant fetal asphyxia and uterine rupture, amniotic fluid embolism, perinatal mortality, and HIE in surviving infants. 46 Because of these concerns, we decided to limit the use of misoprostol in labor to inductions in a nonviable fetus.

Good teamwork promotes professional integrity and is essential in delivering optimal patient care, ⁴⁷ and failure in communication and teamwork is often cited as a common cause of adverse events. ^{6,48,49,50} We found that teamwork can be further improved in labor and delivery by maintaining an electronic comprehensive communication board as the essential hub for communications among staff.

Sleep deprivation can impair safety, and establishing a laborist program has been recommended to improve safety. The hiring of a laborist allowed our obstetricians to work reduced inhospital hours and likely contributed to the improved safety climate and improved outcomes at our institution.

The traditional erasable labor and delivery white board usually reflects situational awareness, the state of knowing what is going on with patients and in the unit. Unfortunately, most obstetric units still use a dry erasable white board that has severe limitations, including accessibility and space limitations. We believe that the implementation of a centralized, internet-based comprehensive electronic "white board" with automatic alarms and color-coding¹⁸ significantly improved situational awareness and thus may have contributed in decreasing adverse outcomes and reducing compensation payments.

Historically, EFM tracings have been interpreted with wide variations among the labor and delivery staff, often leading to inconsistent decision making in response to tracing interpretation. MacEachin et al⁵¹ showed improved communication as well as improved safety perception by the staff with the use of a common EFM language after a multidisciplinary EFM training program.

Our study is limited by its retrospective nature. There were numerous changes made over several years, so that the impact of any one change on a single outcome measure cannot be individually determined. It is possible, that because of the retrospective nature of this report, there may have been other unknown factors that contributed to the reduction of compensation payments and sentinel events.

To paraphrase Ralph Waldo Emerson (1803-1882) who said "Life is a journey not a destination," we believe that achieving patient safety on labor and delivery is a journey, not a destination.

Improving patient safety requires extensive and considerate changes, physician and staff cooperation, constant vigilance, flexibility, and rapid adaption based on new experiences and it may take considerable time to reap financial benefits in the future.

Making significant changes on a labor and delivery unit including such features as the implementation of a standardized oxytocin protocol, electronic charting, team training, and improving situational awareness through a central communication system, should be considered by all obstetric services. As we have shown, these changes can increase patient safety, decrease sentinel events, and, as a consequence, reduce compensation payments.

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U-M's efforts to encourage disclosure of medical errors decreased claims

Admitting mistakes did not lead to more malpractice costs



Meet the expert: Richard C. Boothman

Ann Arbor, Mich.— The University of Michigan's program of full disclosure and compensation for medical errors resulted in a decrease in newclaims for compensation (including lawsuits), time to claim resolution and lower liability costs, according to a study published Aug. 17 in the Annals of Internal Medicine.

"The need for full disclosure of harmful medical errors is driven by both ethics and patient safety concerns," said lead study author, Allen Kachalia, M.D., J.D., Medical Director of Quality and Safety at Brigham and Women's Hospital. "However, because of fears that disclosing every medical error

may lead to more malpractice claims and costs, disclosure may not happen as often and consistently as we would hope."

In 2001, the University of Michigan Health System launched a comprehensive claims management program that centered on full disclosure with offers of compensation for medical errors. Under this model, U-M proactively looked for medical errors, fully disclosed found errors to patients and offered compensation when at fault. Researchers conducted a retrospective before-and-after analysis to determine how the UMHS model affected claims and costs. Reviewing claims from 1995 to 2007, researchers found a decrease in newlegal claims (including the number of lawsuits per month), time to claim resolution, and total liability costs after implementation of the disclosure with offer program.

"The decrease in claims and costs may be attributed to a number or combination of factors," says Kachalia. "We found a 61 percent decrease in spending at the UMHS on legal defense costs, and this supports the possibility that patients may be less likely to file lawsuits when given prompt transparency and an offer of compensation."

Researchers hope that this study will alleviate the fears associated with disclosure and will further encourage efforts to disclose all harmful medical errors.

Richard C. Boothman, chief risk officer at the University of Michigan and a co-author of the study, says the research proves that a policy of fully disclosing errors does not appear to lead to skyrocketing medical costs.

"This shows that over time, hospitals can afford to do the right thing," Boothman says. "It demonstrates what we have believed to be true for some time: the sky won't fall in by pursuing a pro-active and honest approach to medical mistakes."

But Boothman adds that reducing costs is not the main motivation behind the U-M policy. Changing the culture to encourage caregivers to admit mistakes also has improved patient safety, which is much more difficult to measure, he says.

"We cannot improve if we're not honest about mistakes. By engaging the patient early — and mostly listening more than talking at first — we get a fuller view of what happened, a better view of what it looked like to the patient, facts that may not be apparent from the chart alone. Engaging patients and families early even before we have reached our own conclusions allows us to get a more accurate view of what happened and provides the opportunity to correct any misimpressions and misunderstandings for everyone concerned," says Boothman.

"We are all in this together. We support our staff best by being honest about mistakes because without that honesty, we'll never fix the problem, other patients may get hurt and we'll expose our staff to that heartbreak again, too. Honesty is the key to improving and hurting no one else is the best risk management I can imagine."

Additional authors: Samuel R. Kaufman, M.A., Susan Anderson, M.B.A., M.S.N., Kathleen Welch, M.S., M.P.H., Sanjay Saint, M.D., M.P.H. and Mary A.M. Rogers, Ph.D, M.S.

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The University of Michigan Health System includes the U-M Hospitals & Health Centers, which comprises three hospitals and dozens of outpatient health centers and clinics; the U-M Medical School with its Faculty Group Practice and extensive research and education programs; the clinical operations of the U-M School of Nursing; and the Michigan Health Corp. The three U-M hospitals are University Hospital, C.S. Mott-Children's Hospital, and Von Voigtlander Women's Hospital. UMHS has been recognized numerous times for excellence in patient care, including 15 years on the honor roll of "America's Best Hospitals", as compiled by U.S. News & World Report. The U-M Medical School is one of the nation's biomedical research powerhouses, with total research funding of more than \$420 million, and consistently achieves high rankings for excellence in the education and training of physicians and biomedical scientists. For more on UMHS, see www.med.umich.edu.

Brigham and Women's Hospital (BWH) is a 793-bed nonprofit teaching affiliate of Harvard Medical School and a founding member of Partners HealthCare, an integrated health care delivery network. For more information about BWH, please visit www.brighamandwomens.org.

First Do No Harm

Last year there wasn't a single fatal airline accident in the developed world. So why is the U.S. health care system still accidently killing hundreds of thousands?

The answer is a lack of transparency.

By Marshall Allen

Georgeanne Mumm's surgeon emerged from the operating room with welcome news for her worried family. He had removed her cancerous kidney, he said, and her outlook looked good.

The surgeon failed to mention, however, that he also had accidentally removed part of her pancreas, having mistaken it for a tumor. Nor did he mention that he had in-advertently cut the blood flow to her spleen, damaging it irrevocably. Only an emergency operation by another doctor the next day kept Georgeanne from dying right then and there.

Now the fifty-six-year-old Mumm sits alone in her trailer in rural Nevada. She is unable to work due to her disability but is still on the hook for about \$300,000 in medical expenses related to her disastrous contact with the U.S. health care system.

Why do we keep hearing stories like this? Twelve years ago, the Institute of Medicine issued a landmark report showing that medical errors in U.S. hospitals kill up to 98,000 Americans a year. In 2000, another estimate, published in the Journal of the American Medical Association, which included fatalities resulting from unnecessary surgery, hospital-acquired infections, and other instances of harmful medical practice, put the total annual death toll at 250,000.

By that figure, contact with the U.S. health care system was the third leading cause of death in the United States, just behind all heart disease and all cancer. People responded to the alarm. Task forces were convened, congressional investigations launched, op-eds written. Yet as hard as it may be to believe, American medicine is, if anything, even more dangerous today.

In November 2010, the U.S. Department of Health and Human Services issued a study that covered just the 15 percent of the U.S. population enrolled in Medicare. It found that each month one out of seven Medicare hospital patients is injured—and an estimated 15,000 are killed—by harmful medical practice. Treating the consequences of medical errors cost Medicare a full \$324 million in October 2008 alone, or 3.5 percent of all Medicare expenditures for inpatient care. Another recent study looked at the incidence of avoidable medical errors across the entire population and concluded that they affected 1.5 million people and cost the U.S. economy \$19.5 billion in 2008. The Centers for Disease Control and Prevention have estimated that almost 100,000 Americans now die from hospital-acquired infections alone, and that most of these are preventable.

People like Carole LaRocca are the human face of this travesty. One day recently I sat at the seventy-four-year-old's kitchen table as she broke down in tears. She was weeping not because of the hospital-acquired infection that almost took her life, but because of the \$3,676 bill she faced for the antibiotics she needed to treat the harm done to her by her hospital stay. Every month she pays \$25 of her meager fixed income toward the debt, and is still hounded by bill collectors.

A cynic might say it's no surprise that American medicine fails to put safety first, since doctors and hospitals often make money by treating those they injure. There is, however, also a deeper and more systematic reason for the continuing toll of injury and death caused by the U.S. health care system: we don't know who's failing and who's succeeding. Plenty of U.S. hospitals have dramatically improved their safety performance. The best have virtually eliminated the deadliest hospital-acquired infections, even as lethal microbes have evolved to become more contagious and resistant to treatment. If every health care provider adhered to the highest standards of patient safety and evidence-based medicine, hundreds of thousands of lives could be saved, to say nothing of the billions of dollars spent on treating complications—but good luck discovering for yourself which hospitals are safe and effective and which aren't.

That's because the public, the payers, and the providers themselves typically lack access to the data necessary to make such a life-and-death determination. In the airline industry, if a pilot so much as accidentally makes a wrong turn moving away from the gate, anywhere in the world, the event is instantly recorded in global databases and scrutinized by government agencies and the industry itself. The knowledge gained from this continuous process leads to big and little changes in aviation protocol, equipment, and personnel. As a result, there was not a single airline fatality anywhere in the developed world last year.

In health care, by contrast, patient safety experts often remark that the death toll from medical errors in U.S. hospitals is equivalent to three jumbo jets falling out of the sky and killing all the passengers on board every forty-eight hours. But even the most egregious errors go largely unreported, and when they are reported, they are often buried and ignored. For the most part, all the public gets to hear about are industry-wide estimates and statistical averages of the kind presented above. Because we lack specific knowledge of where these injuries are occurring and under what circumstances, we can't know precisely what to do about the ongoing catastrophe or whom to reward when specific solutions are found.

Fortunately, there is much that can be done—even by mere journalists willing to submerge themselves in some data. Not long ago, my colleague at the Las Vegas Sun, Alex Richards, and I set out to identify these cases of preventable harm and publish them. In Nevada, regulators require hospitals to submit a record of every inpatient stay, a policy originally intended to monitor costs. Based on billing records, each file provides a patient's age, gender, and race, as well as the conditions diagnosed and the procedures received during his or her hospital visit.

And in 2008, the federal government started asking hospitals nationwide for one additional piece of data. Stung by the money it was paying under Medicare to treat injured patients, hospitals were required to report with a "yes" or a "no" whether each medical condition was present when the patient was admitted. This makes it possible to identify how may patients acquired preventable injuries while at the hospital—problems like severe bedsores, bloodstream infections caused by central-line catheters, and falls that resulted in a broken bone.

Shaking the data out of Nevada's state government wasn't easy, and crunching through 2.9 million inpatient billing records was also involved, as well as interviews with more than 250 nurses, doctors, hospital administrators, and injured patients to make sense of it all—but we eventually prevailed and launched a five-part series based on what we discovered. (The entire series is available at www.lasvegassun.com/hospital-care.) Not surprisingly, given the picture that health care quality experts paint of the U.S. health care system as a whole, we found that the safety performance of Las Vegas hospitals was alarming. In 2008 and 2009, for example, we identified 3,689 Las Vegas patients who suffered preventable harm, including 2,010 who became infected by one of two nearly untreatable and often fatal bugs: methicillin-resistant Staphylococcus aureusbetter known as MRSA—andClostridium difficile. In 354 of the total cases, the patient died in the facility. With the help of other public documents, we established that only about one in ten of these and other preventable errors was ever brought to the attention of authorities, as is required by state law, much less analyzed for lessons learned.

The real power in our reporting, however, came from the transparency and accountability it imposed on the local health care system. We published the total number of injuries and infections and their rates for each hospital in Las Vegas. Under pressure from hospital lobbyists, the Nevada state government had long refused to do this, as is common in other states as well. But we saw good reasons for naming names. So, for example, we posted a tool on the Sun's website that allows users to compare the rates of MRSA and Clostridium difficile infections in different Las Vegas hospitals. As it turns out, the MRSA infection rates range from 24 per 1,000 discharges at Desert Springs Medical Center, to a "mere" 7.6 at Spring Valley Hospital, eight miles down the road.

To put this more-than-threefold difference into context for our readers, we published a series of accompanying stories pointing out that infection control is hardly rocket science. According to Dr. Peter Pronovost, a professor at Johns Hopkins School of Medicine and a national patient safety leader, prevention of central-line catheter infections involves little more than a simple five-step checklist:

- · Wash hands.
- Wear sterile gloves, hat, mask, and gown and completely cover the patient with sterile drapes.

- If possible, do not place the catheter in a patient's groin, where it can more easily become infected.
- Clean the catheter insertion site on the patient's skin with chlorhexidine antiseptic solution.
- Remove catheters when they are no longer needed.

After Pronovost partnered with Michigan hospitals to study the effectiveness of the checklist, the reduction in infection rates saved an estimate \$100 million and 1,500 lives over just an eighteen-month period. In 2002, Dr. Rajiv Jain of the Pittsburgh Department of Veterans Affairs Medical Center introduced a commonsense method used throughout Europe to drive down the number of hospital-acquired MRSA infections: swab the noses of patients before they are admitted, and if they test positive for MRSA, isolate them from other patients. This simple protocol has reduced hospital-acquired MRSA infections by 59 percent at both the Pittsburgh VA and other hospitals that have followed its example. At some VA hospitals, MRSA infection rates have been lowered to almost zero.

It's still too early to tell how the market share or quality of care at different Las Vegas hospitals may be affected by exposure to our bit of sunshine, but we've already seen the leaders of at least two institutions publicly reporting the errors and infections that take place in their hospitals and vowing to make improvements. Meanwhile, insurance companies can see the same broad disparities in patient safety, and some now use our data to pressure hospitals to improve quality. State regulators responded to the revelations by using our methods to verify our findings in the same billing records, and then launching investigations of the individual cases of patient harm. **Transparency is a potent antidote for complacency.**

Because of the lack of national standards for measuring and reporting harm to patients, we were unable to show definitively, with a few exceptions, that care in Las Vegas is any more dangerous than anywhere else. It's telling that some leaders of the local medical establishment jumped on this point. "You're looking at the problems in Las Vegas and saying there are problems here, no one is denying that," said Dr. Ron Kline, president of the Nevada State Medical Association. "But the argument would be that those similar problems exist in other places. To some degree you can't eliminate them."

Unfortunately, this attitude is typical among health care leaders. When I showed our data about accidental sufgical injuries to Dr. Jim Christensen, an allergist who also oversees quality improvement at Spring Valley Hospital in Las Vegas, he was nonplussed. "I see these all the time," he told me. Asked if he had become inured to the problem, he said that surgery is "like working on the car with the engine going. Sometimes something slips, but they recognize the injury right away and repair it. As long as that doesn't go beyond the published error rate, I'm fine."

What these and many other like-minded health care professionals are saying can be put another way: Never mind that errors committed by individual hospitals might be leading to hundreds or thousands of annual deaths and injuries, or that safety measures put in place by other hospitals show that most of these casualties are avoidable; as long as the rate of medical error or infection at any given hospital is in line with the national average, that is good enough.

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Kerry O'Connell, a fifty-four-year-old construction executive from Colorado, scoffs at this mind set. Several years ago he became infected with potentially lethal bacteria during surgery to repair a broken elbow. O'Connell says that it took weeks of procedures to flush out his wound, and months of infusions with potent antibiotics to kill the resistant bug, yet doctors and hospital administrators refused to accept responsibility for the infection. Meanwhile, they charged O'Connell and his insurance company \$65,000 for the treatment. Galvanized by the injustice, O'Connell became a patient safety advocate and has adopted a clever prop to get his big point across. When he attends conferences on patient safety, he wears a name tag that says, "The Numerator."

When people inevitably ask him what that means, he launches into the explanation. It's easy to forget, he says, that even in hospitals where medical error rates are no worse than average, the numerator in that ratio—the number of actual people victimized—remains large and unacceptable. "I call infection rates sedatives for health care workers so they can sleep at night," O'Connell said. "They keep tracking these rates and comparing to each other and saying 'We're not so bad.' But the only thing that counts in the end is how many people got infected."

If the airline industry and its regulators had clung to the same attitude, the average rate of airline fatalities would likely be little better than it was in the 1950s, when flying was at least three times as dangerous, on average, as it is today. It's only human nature to call average good enough, particularly when what you are doing is difficult. Moreover, when people are engaged in inherently dangerous activities that they believe bring great benefit to society—whether it is serving their country in combat, or moving passengers at 600 miles an hour in and out of the wild blue yonder—it's understandable that they tend to overlook or dismiss any avoidable harm caused by their actions. Dr. Thomas Lee, an associate editor at the New England Journal of Medicine and a professor at the Harvard School for Public Health, notes how this same process of moral disengagement affects doctors and hospital administrators. They are reticent to acknowledge patient harm, he says, because they're too busy highlighting the diseases cured and lives saved.

To overcome this natural tendency toward moral disengagement—or what safety experts in other fields call "normalized deviance"—we need in health care what the airline and many other industries already have: a process for systematically recording specific errors and near misses and for making them widely known so that everyone can learn from them. Dr. Peter Pronovost, the safety expert from Johns Hopkins, recommends creating a similarly robust, nationwide system for spotting, measuring, and reporting

instances or harbingers of harmful care, with spot audits of medical records to assure compliance. This was also a recommendation of the ground-breaking 1999 "To Err Is Human" report. Following the example of the aviation industry (and of the VA health system, incidentally), this system should also include a process that allows people who witness or commit errors and near misses to report them anonymously.

Public reporting will be bolstered, to a limited degree, under the fine print of Obama's Affordable Care Act. The new law says that certain injuries and infections that take place in hospitals will be published on Medicare's Hospital Compare website. Hospitals will also be rewarded or penalized according to how certain readmission rates and hospital-acquired injuries compare to national averages. (As this story was going to press, the Centers for Medicare and Medicaid Services were formulating regulations that go further than any previous efforts, using both carrots and sticks to get hospitals to make care safer.) But here again, the mind set is not zero tolerance of error, but merely a focus on how different hospitals compare to the mediocre safety performance that pervades the industry. Moreover, the new law applies only to acute care hospitals, leaving out nursing homes and other long-term care facilities. It will only include harm to Medicare patients, a subset of the overall population. And the system will not be able to capture some of the most common types of injuries to patients, such as those caused by medication errors.

The provisions of the Affordable Care Act are a step in the right direction, but they don't go far enough. Implementing and operating a nationwide system that captures all harm to patients also requires that the U.S. health care system at last move out of the nineteenth century and replace paper records with open-source; truly integrated information technology of the kind the VA has pioneered. Electronic medical records, if they are written in compatible, open-source computer languages, have the potential to form vast databases that researchers, regulators, and practitioners themselves can easily mine to spot dangerous or ineffective practice patterns. Unfortunately, though many health care providers are busy installing health IT using federal stimulus dollars, most are installing propriety software that will leave data locked in "black boxes" and that have limited value in promoting transparency. (For more information on this subject, see Phillip Longman, "Code Red," July/August 2009.)

Done right, a fully digitalized and integrated medical record system would also by itself prevent many serious errors, such as the thousands that occur every year when pharmacists misread a doctor's scribbled prescription. Lest you think such matters are no big deal, the Institute of Medicine estimates that the average hospital patient in the U.S. is subject to at least one medication error per day (wrong med, wrong dose, wrong time, wrong patient), and that the financial cost of treating the harm done by these errors conservatively comes to \$3.5 billion a year. An integrated digital records system would also make it much easier to monitor and curb the overuse of treatments that are both costly and dangerous. For example, Americans are exposed to so many CT scans, many of them redundant, that, according to the New England Journal of Medicine, the resulting radiation exposure

may be responsible for as much as 2 percent of all cancer deaths in the country.

With such a robust, data-driven system of safety promotion at last brought to bear in health care, average performance will no longer seem good enough. Health care providers, employers choosing health care for their workers, and patients seeking the best care will all demand more. The benchmark for any given hospital to meet would thus become what it should have been all along: the refusal to tolerate even one case of preventable harm to a patient. Without such demonstrable standards of performance, there is little hope that the quality of health care can improve—whether the system is "socialized," "market driven," or any combination thereof.

Some doctors and hospital administrators will object on principle. When O'Connell, aka "The Numerator," asked his surgeon about the moral implications of billing patients for treatments made necessary by sloppy medical practice, the response he reports receiving was disheartening: "We're like lawyers," O'Connell recalls the surgeon saying. "We just provide services by the hour and sometimes it works and sometimes it doesn't."

Other medical providers live by a higher standard than this, yet many will still raise all kinds of methodological objections. They will say that their patients tend to be much sicker or older than those treated in other hospitals. Or that the reason their hospital has such high infection rates is that many of their patients come from nursing homes, where lethal bacteria are rampant. (In the case of our investigation, I always pointed out that we were reporting the infections that their own employees had marked as not present at the time the patient arrived, meaning they were acquired in the hospital itself.) And to be sure, certain risk adjustments do need to be made in comparing the performance of one hospital with another.

But these are adjustments that can be made, and made all the more fairly and definitively the more data we have about just who is receiving what treatments and with what results. In no other realm—certainly not any as inherently dangerous as health care—do we accept the argument that meaningful comparisons of results are impossible just because those being compared face somewhat different circumstances. Some airports have shorter runways and are more congested than others; some have to deal with frequent snow or thunderstorms, nearby mountain ranges, or lakes and rivers that attract unusual numbers of flocking birds. No two are exactly the same. Yet we don't therefore conclude that there is no point in comparing the safety record of one airport versus another, much less say that it is acceptable for a certain number of people to be routinely killed on approach or takeoff. We demand that all airports, and everyone else involved in aviation, do what it takes to get accidents to as close to zero as possible, and that they use reams of performance data to make that happen.

Moreover, it's not just the outputs of different health care providers we are concerned with, but their inputs as well. You say many of your infected patients are coming from nursing homes? Why not hold them to higher standards? Why

are you not doing what the Pittsburgh VA is doing and testing all your patients for infection before they get out on the wards? Why don't you have sensors in hospital rooms, as some hospitals now do, that sound an alarm if anyone exits the door without having first washed his or her hands? For that matter, why not take up the suggestion of Paul O'Neill, the former treasury secretary who pioneered industrial safety as CEO of Alcoa and is now a leading voice on patient safety: have a big sign posted at the front door of the hospital, as nearly all factories and construction sites do, that reminds workers as they come on each shift just how many days it has been since the last medical error or hospital-acquired infection? In short, just exactly what have you done to promote a culture of safety?

Experience has shown that when hospitals and doctors can answer that question forthrightly, and when they are open and honest about their mistakes and show they are taking steps to fix them, they are much less likely to face malpractice suits. In 2004 the University of Illinois Medical Center in Chicago began flagging cases of harm and unsafe conditions that could cause injuries—up to 7,000 reports a year. It also began admitting and apologizing for its mistakes, conducting investigations of harmful incidents that are open to patients and their families, and even offering financial compensation when necessary. The program has lowered the number of malpractice claims and the amount of payouts, while increasing trust and leading to hundreds of patient safety improvements. The hospital's methods boil down to what any one of us would instruct a child to do when he makes a mistake: stop making excuses, and take responsibility. The facility is now considered a hational patient safety pioneer, and its methods are being expanded through a federal grant to nine other hospitals in the Chicago area.

This is what current best practices in patient safety look like. They could be even better if consumers and medical experts had the data they need to determine each hospital's progress in promoting safety. We know this works in other inherently dangerous industries. Why should health care be an exception?

We all understand that medicine is increasingly complicated and that hospitals are increasingly filled with patients who would have died years ago were it not for the wonders of modern medicine. But the Hippocratic oath says, "First do no harm." Precisely because health care is becoming more and more complex, and therefore inherently dangerous, it will continue to cause more and more deaths and injuries until we put safety first.

Marshall Allen is a health care reporter for the Las Vegas Sun

By Marcus E. Semel, Stephen Resch, Alex B. Haynes, Luke M. Funk, Angela Bader, William R. Berry, Thomas G. Weiser, and Atul A. Gawande

Adopting A Surgical Safety Checklist Could Save Money And Improve The Quality Of Care In U.S. Hospitals

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ABSTRACT Use of the World Health Organization's Surgical Safety
Checklist has been associated with a significant reduction in major
postoperative complications after inpatient surgery. We hypothesized that implementing the checklist in the United States would generate cost savings for hospitals. We performed a decision analysis comparing implementation of the checklist to existing practice in U.S. hospitals. In a hospital with a baseline major complication rate after surgery of at least of percent, the checklist generates cost savings once it prevents at least five major complications. Using the checklist would both save money and improve the quality of care in hospitals throughout the United States.

Four of the eight pilot sites were in high-income countries with well-developed health care infrastructures; one site was in the United States. Among these four sites, there was a 30 percent reduction in major complications after the introduction of the checklist.

With evidence that systematic use of sheaklists.

With evidence that systematic use of checklists can result in decreased rates of surgical complications³ and of catheter-related bloodstream infections,⁴ the use of this type of intervention is gaining acceptance.^{5,6} However, one line of criticism of checklists is that they may be cost-ineffective because of the time, effort, and varying levels of risk involved.⁷ In this paper we examine the costs of implementation and use of the WHO Surgical Safety Checklist in the United States to determine whether or not it reduces costs at the hospital level.

Study Data And Methods

We performed a decision analysis of implementation and use of the checklist in a U.S. hospital over a one-year period. The analysis was performed from the hospital's perspective with respect to costs. Costs were adjusted for inflation to 2008 dollars based on the Consumer Price Index

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he World Health Organization (WHO) launched the Safe Surgery Saves Lives campaign in January 2007 to improve consistency of surgical care and adherence to safety practices. As part of the campaign, the Surgical Safety Checklist was created through an international consultative process. The checklist is a two-minute tool, much like the checklist a pilot uses before takeoff, and is designed to help operating room staff improve teamwork and ensure the consistent use of safety processes.1 It consists of a series of checks that occur before the delivery of anesthesia, before any incision is made in the skin, and before the patient leaves the operating room (the components are shown in list form in Appendix Exhibit 1).2 Examples of the checks are confirming that appropriate antibiotics have been given to prevent infection, the necessary equipment is available, and no members of the team have any unaddressed questions or concerns before proceeding with the op-

In a pilot study of systematic implementation of the checklist, its use markedly decreased complications for patients undergoing noncardiac surgery in eight diverse international hospitals.³

and the Medical Care Price Index.8

We did not apply a discount rate, given the oneyear time horizon. Costs associated with the checklist were divided into one-time start-up costs for its implementation and recurrent costs for its use.

IMPLEMENTATION COSTS: We based our estimates of implementation costs on experiences at the eight pilot sites in the Safe Surgery Saves Lives Study; experience at our own institution, Brigham and Women's Hospital; and personal communications with staff of U.S. hospitals that had adopted the checklist (personal communication between Alex Haynes and Katrina Golub on December 10, 2008; personal communication between Angela Bader and Kristen Styer on January 25, 2010).

Implementation of the checklist generally requires collaboration among the departments of surgery and anesthesia and the nursing staff of the operating room. Representatives from each group work together to introduce the checklist to their staff, modify it to meet the conditions in their hospital, and make appropriate systems changes to ensure successful use of the checklist.

Champions of the checklist or leaders in each department, together with an implementation coordinator, generally oversee the implementation process. The coordinator, usually a quality improvement officer with a bachelor's or master's degree, helps facilitate the hospital's adoption of the checklist.

At both our institution and the U.S. pilot study site, senior clinicians in leadership roles within their own departments were involved in the implementation process. These clinicians championed the checklist's use within their departments and worked with other departments to provide multidisciplinary leadership. The time commitment of individual checklist champions varied between institutions. For our analysis, we applied the highest estimate to all three champions. The time commitment of the implementation coordinator was similar at each institution.

We defined the cost of implementation as the opportunity cost of the work that would have otherwise been performed by the three department checklist champions and the implementation coordinator. We calculated this cost by summing the time spent on implementation multiplied by the mean hourly wage for each champion and the coordinator. 10

Based on the experience at our institution and the U.S. pilot study site, we estimated the time spent on checklist implementation at 40 hours for each champion and 120 hours for the implementation coordinator. Using this estimate, we arrived at an implementation cost of \$12,635 for our base-case analysis.

To date, the checklist has commonly been introduced to clinicians during a portion of a grand rounds—the presentation of a particular patient's case or a didactic lecture to a group of clinicians—or at a regularly scheduled staff meeting. Because clinicians do not usually see patients or operate during this time, they do not have to choose between learning about the checklist and generating revenue. In this case, the opportunity cost of the time spent discussing the checklist is forgone educational or meeting time, which we considered negligible and excluded from our analysis.

PER USE COSTS Although there has been concern about the time required to perform the checklist, institutions—including our own—that have been early adopters of the tool have not experienced decreased productivity or disruptions in work flow. Therefore, in our base-case analysis we assumed that the cost of time spent performing the checklist in the operating room was zero. However, in our sensitivity analysis, we varied the cost of time spent running through the checklist.

Most of the checklist items have little to no direct cost, as they tend to consist of verbal confirmations that a routine safety measure has been performed. Thus, consistent performance of these checklist items would be expected to result in minimal added cost.

An exception is antibiotic prophylaxis, or the use of antibiotics to prevent infection, which requires the use of a consumable good as opposed to the performance of a verbal check. Accordingly, we calculated the per use cost of the checklist by estimating the increase in the appropriate use of antibiotic prophylaxis observed after the implementation of the checklist.

In the pilot study of eight hospitals, antibiotic prophylaxis increased by 26.5 percent after implementation.³ We applied this rate of increased antibiotic use to the cost of using the antibiotic cefazolin for prophylaxis, or of using vancomycin with patients allergic to the antibiotics penicillin or cephalosporin.^{12,13} Based on these assumptions, the per use cost of the checklist was estimated at \$11 for our base-case analysis.

We excluded costs associated with surgical site marking as well as the use of pulse oximetry, or measurement of blood oxygenation levels. Although the checklist is intended to ensure that surgery sites are marked, it is not clear whether the practice of marking actually increases with use of the checklist. The Safe Surgery Saves Lives Study did not assess adherence to this safety measure. We also excluded the cost of pulse oximetry because its use is nearly universal in the

United States.

The resulting range for per use checklist costs in the sensitivity analysis was \$5.50-\$22.00.14

costs and rates of surgical complications. We estimated the cost of a major surgical complication from the literature. In our basecase analysis, this cost was \$13,372 after adjusting for medical price inflation. Because our analysis is from the hospital's perspective, we did not include outpatient costs or costs to the patient.

There is no national estimate of complication rates across all types of surgery. In addition, the operating rooms chosen for study in the pilot sites had high baseline complication rates. As a result, we used an estimate of complication rates from the literature. This estimate was based on a retrospective review of discharges for all types of surgical procedures from hospitals in Utah and Colorado. Based on this estimate, the complication rate for our base-case analysis was 3 percent.

The relative rate of reduction of major complications with the checklist was estimated from the reduction in complications observed in the high-income sites in the Safe Surgery Saves Lives Study.³ Although there was a 30 percent relative reduction of major complications at those sites,³ we assumed a 10 percent relative reduction in major complications with the checklist to account for the possibility that other hospitals may experience less dramatic results. We did not attribute any reduction in postoperative mortality to the checklist because the reduction observed at high-income pilot sites was not statistically significant.

We estimated the annual number of inpatient operations performed at the hospital level based on the literature, in conjunction with data from the American Hospital Association regarding the proportion of operations that are inpatient and the number of hospitals performing surgery. ⁷⁷⁻¹⁹ For our base-case analysis, we estimated that

4,000 noncardiac inpatient operations occur each year.

cost analysis To determine whether the checklist produces savings, we compared its use to current practice. The cost associated with current practice was calculated by multiplying the number of noncardiac inpatient operations performed per year by the complication rate and the cost per major complication. To calculate the cost of the checklist, we summed the per use cost, implementation cost, and cost from major complications. We then calculated its net cost by subtracting the cost of checklist use and implementation from the cost of current practice.

In addition to our base-case analysis, we completed one-way sensitivity analyses and threshold-level analyses. A summary of the inputs for our base-case and sensitivity analyses is included in Exhibit 1.

Study Findings

BASE-CASE ANALYSIS When compared to current practice in the base-case analysis, the implementation and use of the checklist would save \$103,829 annually for a hospital that performed 4,000 noncardiac operations per year. This equates to a savings of \$25.96 per operation performed.

For every complication averted, there is a net savings of \$8,652. To achieve cost savings, at least five major complications would need to be prevented with use of the checklist. Cost savings are possible when the additional cost per major complication is as low as \$1,574 (Exhibit 2).

THRESHOLD ANALYSIS For a given baseline complication rate, cost savings achieved with the checklist increase as the relative reduction in complications increases (Exhibit 3). At a 3 percent baseline complication rate, if there is a relative preduction in complications of only 1 percent—and the complication rate drops to

EXHIBIT 1

Base-Case And Sensitivity Analyses	Inputs, Study	Of Surgical Safety Checklist Use

	Range for sensitivity					
Input Amount	analys is	Notes in text				
Checklist implementation cost	≥ \$6,3 18 - \$25,270	10				
Per use checklist cost	\$5 50~\$22 00	3 11 14				
Cost per major inpatient complication \$13,372	\$6,685- \$ 26,744	15				
Baseline major complication rate	1_1704	16. 20				
Relative reduction in major complications with the checklist 10%	5-30%					
Noncardiac inpatient operations per year 4,000	1,000-8,000	17, 18, 19				

sources Notes 3, 10, 11, 14-20 in the text, as indicated in far-right column.

EXHIBIT 2

Base-Case Results For Implementation And Use Of The Surgical Safety Checklist

Cost savings		Minimum needed to achieve	e savings		et.	
Per year \$103,829	Per complication averted \$8,652	Per operation \$25.96	Number of complications averted > 5	Cost per complication > 1.574	Baseline complication rate > 1.06%	Relative reduction in complications

SOURCE Authors' calculations. NOTE Amounts in 2008 U.S. dollars.

2.97 percent—the checklist costs the hospital \$40,589 per year. When the relative reduction in complications increases to at least 3.53 percent—and the complication rates drops to 2.89 percent—the checklist saves the hospital money, as demonstrated in the base case.

If complications are reduced by 30 percent, as observed in high-income sites in the Safe Surgery Saves Lives Study, savings would increase to \$424,757 per year of the baseline complication rate were as high as 17 percent; savings would be \$2,671,253 per year.

As the relative reduction in complications increases, the initial complication rate required for a hospital to achieve cost savings with the checklist decreases (Exhibit 4). A baseline complication rate of at least 2.12 percent would lead to cost savings with the checklist if a 5 percent relative reduction in complications is achieved. If there is a 15 percent relative reduction in complications, the checklist saves the hospital money if the initial complication rate was as low as 0.71 percent.

SENSITIVITY ANALYSIS One-way sensitivity analysis demonstrated that the checklist saves money when the baseline complication rate is ≥ 0.06 percent or the relative reduction in complications is ≥ 3.53 percent (Exhibit 2). Varying the number of operations per year, the additional cost per major complication, and the cost of implementation and use of the checklist did not affect whether the checklist is cost saving (Exhibit 5).

However, varying each of these inputs separately did affect cost savings by one order of magnitude. When the number of noncardiac inpatient operations is as low as 1,000 per year with a 3 percent complication rate and a 10 percent relative reduction in major complications, the cost savings is \$16,481. If the number of operations increases to 8,000 per year, the cost savings increase to \$220,293.

The variation in cost savings is greatest with variation in the additional cost per major complication, ranging in our analysis from \$23,597 to \$264,293. Cost savings are relatively insensitive to variation in implementation cost, ranging from \$91,194 to \$110,146.

Discussion

This study demonstrates that the adoption and use of the WHO Surgical Safety Checklist is a cost-saving quality improvement strategy. If at least five major complications are prevented within the first year of using the checklist, a hospital will realize a return on its investment within that same year.

Since implementation costs make up the majority of the costs associated with the checklist and do not recur, cost savings may occur beyond the first year of use. Even hospitals that do not prevent five major complications in the first year may still save money as the number of complications averted accumulates over a longer period of time.

COMPARABLE STUDIES A previous study of the use of a checklist to prevent catheter-related bloodstream infections suggested potential cost savings from checklist use. 4 Other studies have

EXHIBIT 3

Checklist Savings Per Year By Compilication Rate And Relative Reduction In Major Complications

Savings :	from	relative	reduction	in	major	com	plications	(\$)	1
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Complication rate						
	1%	5%	15%	20%	30%	
3% 17%	-40,589 34.295	23,597 398.013	184,061 1,307,309	264,293 1,761,957	424,757 2,671,253	
	- ,,	250,015	وي در دود. ۱	1,701,337	2,071,233	

SOURCE Authors' calculations. NOTE Amounts in 2008 U.S. dollars.

suggested that using a daily goals checklist in an intensive care unit is a cost-effective means of reducing hospital-acquired infections.²¹

Our study is consistent with these reports and extends them by finding that the systematic implementation of a simple, relatively inexpensive, low-technology intervention such as a checklist reduces costs.

also realize savings through gains in efficiency. We did not include such savings in our analysis because the causal mechanism for these improvements is not yet clear. However, the use of a "preflight checklist" in Kaiser Permanente Southern California's operating rooms resulted in improved nurse retention, with turnover decreasing from 23 percent to 7 percent.²²

Also, after implementation of Kaiser Permanente's checklist, there was a decrease in the number of operations that were canceled or delayed.²² Additional evidence suggests that operative briefings may actually decrease delays²³ and disruptions to the surgical work flow.²⁴

Because we accounted for cost savings only through the first year of checklist use, we may have underestimated the checklist's potential benefit. Although there may be costs associated with training new hires and with maintaining checklist use with current employees, we suspect that these costs would not be as considerable as the implementation costs.

We also suspect that the benefits from reducing complications would persist, leading to continuing savings. Since the use of the checklist is in its early stages, further investigation of the costs associated with its continued use, as well as its long-term effectiveness, is necessary. For ex-

EXHIBIT 4

Levels of Reduction in Major Complications At Which Implementation Of A Surgical Safety Checklist Saves Money

Percent relative reduction in major	Percent baseline major complication
complications	rate
	≥ 10.59
5	> 2 12
15	≥ 0.71
20 .	> 0.53
30 %	≥036

source Authors' calculations.

ample, hospitals may find over time that more dedicated training in the use of the checklist produces improved results.

be interpreted in its context: the early phases of implementation and use of the checklist. Data on the time required to use the checklist remain limited. However, sensitivity analysis shows that even with added time in the operating room, cost savings persist.

Further, we estimated implementation and per use costs based on the experiences at pilot sites and of early adopters. Although further study of the checklist implementation process and its costs is necessary, we found the occurrence of cost savings to be relatively insensitive to the cost associated with implementation and use. Additionally, we probably overestimated the per use cost of the checklist in our base-case analysis. Antibiotic prophylaxis increased by only 5.3 percent after implementation in high-

EXHIBIT 5

Sensitivity Analysis And Threshold Levels For Implementation And Use Of The Surgical Safety Checklist							
			Minimum relative reduction				
Variable	Minimum and maximum	Annual cost savings (\$)	in complications needed				
Relative reduction in major complications	1%	-40.589	to achieve savings				
	30%	424,757					
Complication rate	1%	-3, 147	≥ 10.59%				
Number of operations per year	17%	852,661	≥ 0.62%				
Namber of operations per year	1,000 a	16,481 220,293	≥ 5.89%				
Cost per major complication	\$6,686	23.597	≥ 7.06%				
	\$26 ,2 44	264,293	≥ 1.76%				
Per use checklist cost	\$5.50 ···	125,829	≥2.16%				
Checklist implementation cost	\$22.00	59,829	≥ 6.27%				
=	\$6,318 \$25,270	110,146 91,194	≥ 3.14% ≥ 4.32%				
		,	≥ 3.4470				

"SOURCE Authors' calculations. NOTE Amounts in 2008 dollars. "Not applicable.

income pilot sites, but we based our cost estimate on the increased antibiotic use of 26.5 percent seen across all study sites.³

Another limitation of this study is that the benefit obtained from the use of the checklist is based on the results of a pilot study that had only four high-income sites. Although there was a statistically significant 30 percent relative reduction in major complications observed in the high-income pilot sites, it is not yet clear to what extent this result will prove generalizable nationwide.

This concern is mitigated by our conservative assumption of a 10 percent relative reduction in complications with the checklist in our base-case analysis. Further, we selected the lowest baseline complication rate available in the literature. 16,18,25 At a 3 percent baseline complication rate, a 10 percent relative reduction in complications results in a complication rate of 2.7 percent—a conservative figure given studies showing higher baseline complication rates.

Although our analysis was at the hospital level, hospitals may not be the sole beneficiaries of savings from the checklist. Payers are thought to bear a greater burden of the financial costs associated with surgical complications, ^{26,27} and they may realize a greater proportion of the savings. Therefore, payers might consider providing hospitals with financial incentives for the implementation and use of the checklist. ²⁸

Preventing medical errors and adverse events is a benefit to society even when it does not reduce costs.

Conclusion

Preventing medical errors and adverse events is a benefit to society even when it does not reduce costs. There are important quality improvement programs that may not save money but that are necessary for improving care.

In the current economic climate, hospital leaders may be sensitive to financial considerations when they decide whether to implement a quality improvement program. However, with the existing evidence for both effectiveness and savings through the use of the WHO Surgical Safety Checklist, hospital leaders around the United States should recommend the adoption of the checklist at their institutions.

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By Robert M. Wachter

Why Diagnostic Errors Don't Get Any Respect—And What Can Be Done About Them

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ABSTRACT The first decade of the patient safety movement achieved some real gains, focused as it was on adverse events amenable to systemwide solutions, such as infections associated with health care and medication errors. However, diagnostic errors, although common and often serious, have not received comparable attention. They are challenging to measure and less amenable to systemwide solutions. Furthermore, it is difficult to hold hospitals accountable, since diagnostic errors usually result from cognitive mistakes on the part of one or more members of the medical staff. Health information technology, better training, and increasing acknowledgment of the problem hold some promise. As approaches to measuring, preventing, and mitigating harm from diagnostic errors are proven to work, it will be important to integrate these approaches into policy initiatives to improve patient safety.

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decade ago, the publication of a report on medical errors from the Institute of Medicine (IOM), To Err Is Human, launched the modern patient safety movement. This report, which estimated that 44,000–98,000 Americans die each year from medical mistakes, led to a steady stream of initiatives designed to improve patient safety.

The topic of diagnostic errors has been strangely absent from the flurry of patient safety activity over the past decade.² This absence is particularly noteworthy given the frequency of these errors. Approximately one in ten autopsies uncovers some disease or condition that—had its existence been known when the patient was alive—would have altered his or her care or changed the prognosis.³

Across a wide variety of clinical conditions, diagnostic error rates average about 10 percent.⁴ Ironically, efforts to improve the quality of health care, without taking into account diagnostic errors, sometimes make a bad situation worse. For example, the Centers for Medicare and Medicaid Services (CMS) recently changed

its recommended "door-to-antibiotic" time for patients with pneumonia—after studies showed that many patients who rapidly received antibiotics, thereby meeting CMS's quality standard, ultimately proved not to have pneumonia.^{5,6}

In this article I describe the reasons for the relative inattention to diagnostic errors in the field of patient safety. I also suggest some changes that would help elevate efforts to fight diagnostic errors to their rightful place among serious safety measures.

The Neglect Of Diagnostic Errors

The pattern of ignoring diagnostic errors began with To Err Is Human.¹ A search of the text of the IOM report finds that the term medication errors is mentioned seventy times, while diagnostic errors appears only twice. This is surprising, since the IOM's famous estimate of 44,000–98,000 yearly deaths from medical errors was drawn from the Harvard Medical Practice Study, which found that diagnostic errors constituted 17 percent of all adverse events—far more than medication errors.¹ Other studies have found

that diagnostic errors account for twice as many malpractice suits as any other type of error.8

Reasons For Lack Of Attention

Why did the IOM pay so little attention to diagnostic errors in its seminal report? First, the IOM committee that wrote the report was dominated by thoughtful individuals whose focus was on improving systems of care. That approach works better with medication errors and other errors of execution than with diagnostic errors.

Second, the momentum for the IOM report came from several high-profile errors that clearly demonstrated systemwide flaws, such as the 1994 death of the *Boston Globe* health columnist Betsy Lehman from a chemotherapy overdose, and the 1995 amputation of the wrong leg of a patient in Florida named Willie King. No diagnostic error had garnered similar public attention.

Third, the IOM wanted to focus on solutions, such as computerized provider order entry and other tools. It is far easier to find solutions for medication errors and other process errors than it is for diagnostic errors.

AFTER THE IOM REPORT The IOM report set the stage for collective inattention to diagnostic errors. Events of the following decade pushed this important subset of safety hazards even further behind the curtain.

Since 1999 and up to the present, a variety of policies have been implemented to promote patient safety and quality of care. Those policies include a more vigorous regulatory environment, increased scrutiny of health care organizations by accreditors such as the Joint Commission, and public reporting of safety and quality measures.

Additional pressure for change has come from employer coalitions such as the Leapfrog Group, which has recommended various strategies, such as the use of physicians called intensivists, who provide special care for critically ill patients. Other approaches include pay-for-performance initiatives and Medicare's recent "no pay for errors" policy. S.10 Each of these efforts was designed to increase the penalty to hospitals and health care systems for failing to keep patients safe or to invest in safety programs.

eration to diagnostic errors was again largely absent from these initiatives. One key reason is the problem of measurement. For example, according to Avedis Donabedian's famous framework¹¹ for thinking about quality improvement efforts—structure, process, and outcome—each of these must first be measured before it can be improved.

In the health care system, a relevant "structure" could be a system for computerized provider order entry, and the measurement would be its presence or absence. An example of a measurable process is whether there was a "time out" before surgery, to double-check that the procedure would be performed correctly. And an example of an outcome measurement is tracking and reporting the rate of bloodstream infections associated with central venous catheters, called central lines.

To date, the safety and quality movements have focused mostly on processes, or activities known to be associated with better outcomes. For certain safety targets, process measurement works well. It is relatively straightforward to measure a series of processes—now popularly called a bundle—to prevent bloodstream infections related to central lines and to encode these processes in a checklist that can be widely disseminated. ^{12,13} But diagnostic errors mostly reflect cognitive miscues, such as failing to adequately consider alternative diagnoses. No comparable series of processes (or structures) has been identified to prevent them.

If there have been few structure or process measures that convincingly correlate with diagnostic errors, why not use outcomes? While outcomes seem attractive as a safety target (they are, after all, what patients are most interested in), they are harder to measure than processes or structures, and the science of case-mix adjustment—which would allow outcomes to be calibrated according to patients' severity of illness—is insufficiently advanced to compare apples to apples in many cases.

Moreover, when it comes to outcome measurement, diagnostic errors present additional challenges. Measuring diagnostic errors generally requires a sophisticated review of a patient's chart; even then, expert reviewers often disagree. Such errors also frequently require lengthy follow-up. For example, a missed diagnosis of lung cancer might not be apparent for years.

Two lists of adverse event outcomes form the core of most national and state systems for reporting medical errors: the National Quality Forum's list of "never events," and the Agency for Healthcare Research and Quality's (AHRQ's) Patient Safety Indicators. Not a single diagnostic error appears among the combined total of fifty adverse events or outcomes.

ADDITIONAL FACTORS There are several other reasons why diagnostic errors have failed to receive the attention they deserve. With a few exceptions, such as missed myocardial infarction, diagnostic errors often do not elicit the visceral dread that accompanies wrong-site surgery. This

is probably because these errors frequently have parency, or pay-for-performance efforts. complex causal pathways and might not be revealed for months or even years.

As mentioned above, none of the examples of medical errors that produced an uproar in the media has involved a diagnostic error. Rather, these high-profile cases have tended to involve terrible medication errors such as the one that led to Betsy Lehman's death or surgical errors such as the amputation of the wrong body part.16

One famous medical error, the death of Libby Zion at New York Hospital in 1984, was attributable at least in part to a diagnostic error. But that became known as a death caused by overworked residents and poor supervision, not as one caused by a diagnostic error.17

The Problem Of Solutions

The fact that many other types of medical errors can now be paired with relatively easy-to-understand solutions, some of which are supported by evidence, has helped make them high priorities for action. For example, some prescribing errors can be prevented by computerized provider order entry; medication administration errors by bar-coding and so-called smart pumps; failure to get rote processes right by the use of checklists; and infections associated with health care by infection control practices, such as thoroughly washing or disinfecting the hands.

In contrast, we do not have much evidence so far that the proposed solutions to diagnostic errors work, partly because they have been so little studied.18 In general, the solutions fall into two main categories.

BETTER THINKING The first might be called "better thinking." This involves appreciating the risks of certain cognitive shortcuts called heuristics, and scrutinizing one's own think ing-a process called metacognition-to try to avoid falling into one of a number of common cognitive traps. 19-21

For example, the heuristic known as "premature closure" occurs when a clinician decides on a single diagnosis and fails to fully consider other diagnostic possibilities.22 Proposed solutions indebiasing,"21 such as asking oneself: "What else could this be?" or "What is the worst thing that could be going on?" Another solution includes building in mechanisms to receive systematic feedback on one's diagnostic decisions, such as by receiving notice when a patient discharged from the hospital is subsequently readmitted with a different diagnosis.20-23 Such solutions may be effective. However, they are not easily implemented through the creation of a checklist or a "bundle," or through measurement, trans-

IMPROVED TECHNOLOGY The second category of proposed solutions for diagnostic errors involves improved health information technology (IT) systems, including forms of computerized decision-support systems. Early systems such as DXplain²⁴ and Iliad²⁵ were initially received with enthusiasm, but they quickly fell out of favor when none lived up to expectations.26

Some, 27 although not all, 28 modern computerized decision-support systems are demonstrating positive results and beginning to generate interest. Many observers believe that the systems will take a giant leap forward when more day-today clinical work is documented electronically. Once providers no longer have to input data into the system outside the normal course of documenting care, effective decision-support systems will be able to provide them with meaningful guidance.

IMPROVED DIAGNOSTIC ACCURACY As Gordon Schiff and David Bates recently emphasized, health IT has the potential to improve diagnostic accuracy in ways other than through computerized decision-support systems.29 Among the features they call for are better ways to filter and organize clinical information, functions that promote provider-to-provider communication, more dynamic problem lists, and the incorporation of diagnostic checklists into the electronic record.29 Moreover, Schiff, Bates, and others have observed that many diagnostic errors, particularly missed diagnoses of cancer in outpatients, may be reduced by systemwide improvements that will allow clinicians to see relevant patient care information from other settings, such as freestanding ambulatory laboratories and imaging centers. 22,23,29,30

Unfortunately, although all of these features may decrease diagnostic error rates, there is little empirical research on their actual impact. In addition, few of today's commercially available IT systems include any of the features discussed.

POTENTIAL FOR MORE ERRORS Interestingly, even as some experts focus on the computer as a fail-safe mechanism, others have emphasized the possibility that increased computerization volve what Pat Croskerry has called "cognitive , could cause even more diagnostic errors. In both professional³¹ and lay^{32,33} publications, concerns have been raised that today's electronic health records promote the copying and pasting of clinical information, instead of its thoughtful analysis;34 foster a focus on completing computerized checklists and templates rather than detailed probing of the patient's history;32,33 and support less thoughtful diagnostic reasoning and more automatic behavior on the part of caregivers.31 As With the potential benefits of health IT for diagrostic accuracy, research regarding these

hazards is relatively sparse. Nevertheless, the concerns seem well founded.

It is clear that solutions for diagnostic errors whether new ways of training people to think or the use of advanced health IT systems—cannot compete very effectively in the battle for resources and attention against less controversial, more easily implemented, and better-researched solutions to other safety problems, such as bar codes, checklists, and standardization.

The Problem Of The Accountable Entity

One final disadvantage for diagnostic errors is the absence of an accountable entity with resources to spend on improvement. Partly because hospitals are scrutinized by accreditors such as the Joint Commission, payers such as CMS, regulators such as state departments of health, and the media, they can be held accountable for errors.

That accountability prompts them to invest time and money in creating safer systems of care. Hospitals have supported the collection of adverse event reports and the performance of root-cause analyses by taking actions such as hiring patient safety officers and installing electronic health records.9

But how can a hospital be held accountable for diagnostic errors, which usually represent cognitive mistakes on the part of its medical staff? Even if it can be held accountable, what can we expect it to do when no solution has been convincingly demonstrated to be effective?

Additionally, there currently is no mechanism to measure and promote diagnostic skills on the part of practicing physicians. Board certification could help accomplish this goal, but it is not mandatory, and physicians are reassessed quite infrequently during the process of recertification. Most boards require physicians to pass a certifying exam only once every ten years, and many older practitioners have been grandfathered out of even this requirement.

What Can Be Done?

If diagnostic errors are to be included under the broad umbrella of patient safety, where they can garner the attention and resources they deserve, a variety of stakeholders will need to take con-

ENCOURAGE RESEARCH First, we need to encourage research on diagnostic errors. Are there training models for physicians that lead to fewer diagnostic errors? Do any existing computerized tools really help? How can we measure diagnostic errors without expensive reviews of patients' charts? These are important questions. and research on them should be supported by federal agencies and foundations that award grants in the area of patient safety.

In the past few years, a group of academic physicians and researchers with an interest in diagnostic errors has begun to promote this research agenda, and AHRQ has provided seed funding for the study of these errors.4 Medical journals should encourage these early research efforts by publishing their findings and otherwise highlighting the importance of diagnostic reasoning. One excellent example is the Interactive Medical Cases series recently launched by the New England Journal of Medicine.

PROMOTE ACTIONS THAT REDUCE ERRORS Second, regulators and accreditors should follow this research and promote activities that decrease the probability of diagnostic errors. For example, if studies show that certain types of training are strongly associated with improved diagnostic performance, hospitals should be required to offer them or ensure that their medical staffs participate in them.

The evidence threshold to promote or mandate practices to improve diagnostic safety should be no different than for other safety solutions. When troubling data appeared regarding medication errors at the time of patient transitions between hospitals and other sites, the Joint Commission required hospitals to implement medication reconciliation—the formal process of identifying the most complete and accurate list of medications a patient is taking—even before there was ironclad evidence that the process reduced such errors. A similar bar should be set for low-risk activities that address key types of diagnostic

use rechnology Third, with an estimated \$20 billion in federal support on the way under the 2009 federal stimulus legislation to promote implementation of health information technology, CMS recently announced regulations for what constitutes "meaningful use" of the technology.35 When evidence emerges that certain types of health IT can decrease diagnostic errors. that technology should be considered in setting criteria for meaningful use.

For example, if evidence links certain types of computerized decision-support systems to improved diagnostic performance, the presence of this technology could be used as a criterion for hospitals' and practicing physicians' receiving federal funds for health IT.

IMPROVE MEDICAL TEACHING Fourth, accreditors of training programs for physicians, such as the Accreditation Council for Graduate Medical Education and the Liaison Committee on Medical Education, should ensure that residencies

and medical schools teach diagnostic reasoning³⁶ and make more creative use of model patients and simulations in that training.

Medical students and residents must be taught not to miss certain key diagnoses. Training programs should not rely on serendipity, trusting that every student and resident will happen to see just the right mix of patients under today's apprenticeship model of clinical training. Rather, diagnostic education should be covered as part of a formal, well-planned curriculum, accompanied by robust evaluation methods.

EMPHASIZE BOARD CERTIFICATION Finally, turning to practicing physicians, the certifying boards have a key, perhaps a dominant, role in reducing diagnostic errors. In the absence of process or outcome measurements linked to diagnostic accuracy, the best assurance that the public can have of a physician's competence in diagnostic reasoning is that he or she is board certified and maintains that certification.³⁷

The boards need to focus on this unique role, ensuring that their initial certification and maintenance-of-certification programs emphasize key elements of diagnostic accuracy. These include whether a physician has the knowledge

base to make correct diagnoses, can use electronic resources effectively to find information, has mature clinical judgment, and can engage in appropriate metacognition. Certifying boards need to include more realistic simulations and allow the use of electronic tools, such as online searches, during portions of their examinations to test all of these competencies.

Conclusion

100

As the quality and safety movements continue to accelerate, the need to elevate diagnostic errors to their rightful place among safety hazards grows ever more pressing. As one vivid example of how far we need to go, a hospital today could meet the standards of a high-quality organization and be rewarded through public reporting and pay-for-performance initiatives for giving all of its patients diagnosed with heart failure, pneumonia, and heart attack the correct, evidence-based, and prompt care³⁸—even if every one of the diagnoses was wrong. Clearly, this anomalous treatment of diagnostic errors must be changed.

This article is largely drawn from the author's keynote address at the first annual Diagnostic Errors in Medicine Conference on May 29–31, 2008, in Phoenix, Arizona, for which the author received an honorarium. The author has an equity interest in or serves on paid advisory boards for PatientSafe Solutions and Epocrates. He has

received fees from QuantiaMD for helping produce a Web-based series on patient safety; honoraria from the American Board of Internal Medicine (ABIM) for serving on its board of directors and executive committee; honoraria for many speeches on patient safety and quality; funding under a contract from the Agency for Healthcare

Research and Quality for editing two patient safety Web sites; and royalties from publishers for two books on patient safety. The author thanks Ann Greiner and Lorie Slass of ABIM for their helpful comments on the manuscript, and the organizers of the first annual Diagnostic Errors in Medicine Conference for their support.

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Widely recognized as a leader in the patient safety movement. Wachter has authored two acclaimed books on this topic!

Internal Bleeding: The Truth behind America's Terrifying Epidemic of Medical Mistakes (2004) and Understanding Patient Safety (2008). He has also published more than 200 articles on quality and safety. In 2004 Wachter received a John M. Eisenberg Award, the nation's top honor in patient safety, sponsored by the Joint Commission and the National Quality Forum. He also was rscently named the tenth most influential physician-executive in the United States by Modern Physician magazine.

Wachter long ago recognized that patients in the hospital are vulnerable to lapses in care, poor care coordination, and treatment errors rooted in hand-offs from one care provider to another. He is credited with coining the term "hospitalist" in a 1996 New England

Journal of Medicine article in which he outlined the critical role that this on-site physician can play in improving hospital care delivery and coordination.

As the editor of AHRQ WebM&M. the Agency for Healthcare Research and Quality's case-based patient safety journal on the Web, and AHRQ Patient Safety Network, the leading federal patient safety Web site, Wachter has been privy to detailed accounts of many egregious quality and safety failures that are discussed in general terms on those sites. He also writes a popular blog, Wachter's World, in which he comments on emerging health policy issues, including patient safety and hospital quality measures and regulatory developments.

By Emily R. Carrier, James D. Reschovsky, Michelle M. Mello, Ralph C. Mayrell, and David Katz

Physicians' Fears Of Malpractice Lawsuits Are Not Assuaged By Tort Reforms

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ABSTRACT Physicians contend that the threat of malpractice lawsuits forces them to practice defensive medicine, which in turn raises the cost of health care. This argument underlies efforts to change malpractice laws through legislative tort reform. We evaluated physicians' perceptions about malpractice claims in states where more objective indicators of malpractice risk, such as malpractice premiums, varied considerably. We found high levels of malpractice concern among both generalists and specialists in states where objective measures of malpractice risk were low. We also found relatively modest differences in physicians' concerns across states with and without common tort reforms. These results suggest that many policies aimed at controlling malpractice costs may have a limited effect on physicians' malpractice concerns.

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lthough analysts disagree about the scope and cost of defensive medicine, physicians consistently report that they often engage in defensive practices and that they feel intense pressure to do so out of fear of becoming the subject of a malpractice lawsuit.

Fear of being sued may compromise physicians' ability to communicate effectively with patients, particularly in disclosing medical errors.³ Physicians with high malpractice insurance premiums, which reflect a risky liability environment, have lower career satisfaction and report more adversarial relationships with patients than do physicians with lower premiums.⁴ Physicians with high premiums are also more likely to order diagnostic testing and hospitalize low-risk patients in some settings.⁵

Federal health reform has heightened concerns about defensive medicine for two reasons. First, the financial and organizational changes wrought by health reform have introduced new sources of stress for health care providers, sharpening their demands for liability reform in exchange for their support on other health reform measures. Second, because it leads to defensive

medicine, liability risk is an obstacle to health reform's ambition of moving physicians toward more cost-effective care.⁶

In this article we report findings concerning perceptions of malpractice risk among a nationally representative sample of physicians. Our objectives were to assess levels of physician concern about malpractice, examine associations between level of concern and physician practice characteristics, and relate these concerns to objective measures of malpractice risk, including state medical malpractice reform laws.

We found that individual physicians' concerns about their own malpractice risk are pervasive, vary across specialties in ways that are likely to reflect underlying malpractice risk, and reflect objective measures of risk across states to a limited degree. Our results suggest that many popular tort reforms are only modestly associated with the level of physicians' malpractice concern and their practice of defensive medicine. The results raise the possibility that physicians' level of concern reflects a common tendency to overestimate the likelihood of "dread risks"—rare but devastating outcomes—not an accurate assessment of actual risk.

Study Data And Methods

DATA Physician data were obtained from the 2008 Center for Studying Health System Change (HSC) Health Tracking Physician Survey, a nationally representative mail survey of U.S. physicians who provide at least twenty hours of direct patient care per week. The survey was sponsored by the Robert Wood Johnson Foundation. The sample of physicians was drawn from the American Medical Association (AMA) Physician Masterfile and included active, nonfederal, officeand hospital-based physicians. Residents and fellows were excluded, along with radiologists, anesthesiologists, and pathologists.

The survey had a response rate of 62 percent (N=4,720). It asked a broad array of questions regarding physicians' demographic and practice characteristics, as well as subjective questions dealing with such issues as career satisfaction and concerns about malpractice.⁷

To assess the association between malpractice concerns and state-level data on malpractice risk and malpractice premiums, we used secondary data from the National Practitioner Data Bank, available on the Kaiser Family Foundation Web site; 8,9 the Medical Liability Monitor; 10 market share reports published by the National Association of Insurance Commissioners;11 and the AMA Physician Masterfile, obtained from the Kaiser Family Foundation Web site.12 Malpractice premium data for obstetrics and gynecology, general surgery, and internal medicine from the Medical Liability Monitor were weighted by market share data from the National Association of Insurance Commissioners-Information on state tort reforms affecting malpractice litigation was obtained from the database of state tort law reforms, developed by Ronen Avraham.13 Each reform was considered separately.

With cross-sectional data, it is difficult to infer a causal association between specific laws and physicians' malpractice concerns. Some states may have adopted multiple laws that changed the way malpractice claims are addressed, including caps on various types of damages, as a way to respond to existing high levels of overall malpractice risk. To capture the temporal relationship between states' policies and physicians' concerns, we used data on medical malpractice laws in effect in 2007, one year before the 2008 physician survey. (See the Appendix for a description of state policies.)¹⁴

ASSESSMENT OF CONCERNS. The survey included questions from a malpractice concerns scale developed and validated by Kevin Fiscella and colleagues. 15-19 The questions asked respondents to indicate how strongly they agreed with the following statements based on a five-point Likert scale, ranging from "strongly disagree" to

"strongly agree": (1) I am concerned that I will be involved in a malpractice case sometime in the next ten years. (2) I feel pressured in my day-to-day practice by the threat of malpractice litigation. (3) I order some tests or consultations simply to avoid the appearance of malpractice. (4) Sometimes I ask for consultant opinions primarily to reduce my risk of getting sued. (5) Relying on clinical judgment rather than on technology to make a diagnosis is becoming risky because of the threat of malpractice suits.

We computed the percentage of statements with which each respondent agreed or strongly agreed, across the five statements. The resulting composite score is reported on a scale of 0 to 100.

We compared regression-adjusted means of the composite score across respondents with different individual and practice characteristics, as well as across physicians in different groups of states as defined by values on various measures of malpractice risk, including enacted tort reforms. We also used regression-adjusted means to compare composite scores between specialty groups and to compare physicians across tertiles (thirds) of statewide malpractice risk.

We controlled for differences in the characteristics of physicians, practices, and patient panels. Those characteristics included physician's sex, years in practice, and practice type; number of physicians in practice; percentage of practice revenue from Medicare and from Medicaid; percentage of patients who suffer from chronic diseases; and percentage of patients who are members of racial and ethnic minority groups. Generally, adjusted means differed little from unadjusted ones.

We further report the results of two distinct subscales representing malpractice concerns (statements 1, 2, and 5 on the malpractice concerns scale) and defensive medicine (statements 3 and 4 on the scale). All analyses used survey weights to adjust for probability of selection and differential survey nonresponse.

LIMITATIONS Our study has limitations. Our measure of malpractice insurance premiums is at the state level and does not reflect the premium burden experienced by individual respondents. Similarly, we do not have any information on individual physicians' awareness of individual tort reforms intended to limit malpractice claims.

We have no measure of claims that are closed but did not result in payment, which nonetheless might cause distress and professional and financial loss to physicians. Performing a statistical adjustment used in previous studies to approximate the number of closed claims did not reveal new significant associations with tort reforms.²

Our sample population excludes radiologists

and anesthesiologists-specialists known to have high levels of concern about malpractice. Finally, our survey measures cannot be interpreted as a direct measurement of defensive medical practices. Rather, our aim was to measure physicians' level of fear or concern about liability, which is a subjective construct.

Study Results

CONCERN ABOUT MALPRACTICE LIABILITY COILcern about malpractice liability is pervasive among physicians: 60-78 percent of them expressed agreement or strong agreement with each of the five statements (Exhibit 1). Physicians agreed most strongly with the statement that it is becoming increasingly risky to rely on clinical judgment, rather than diagnostic testing; 78 percent expressed agreement or strong agreement with that statement. Only 11 percent did not agree with any of the statements.

VARIATIONS IN CONCERN ACROSS SPECIALTIES Malpractice concern varied considerably by specialty. Although we lack objective data on malpractice risk or premiums by specialty, physicians in specialties generally thought to be at higher risk for malpractice claims-such as emergency physicians and obstetrician-gynecologists-expressed greater concern (Exhibit 2). Physicians who disagreed or strongly disagreed with the five statements were more likely to be psychiatrists or general pediatricians.

This pattern was similar for the malpractice concern and defensive medicine subscales. There was some variation among specialties,

VARIATION ACROSS OTHER PHYSICIAN AND

PRACTICE CHARACTERISTICS As shown in Exhibit 3, the level of malpractice concern was associated with several physician and practice characteristics (only characteristics for which there were significant differences are shown in the exhibit; the full set of results is available in Appendix Exhibit 2).14 Physicians with fewer than five years of practice experience had significantly greater malpractice fear—average concern score of 70.4 points—than physicians with more than ten years of experience—average concern score of 64.4 points.

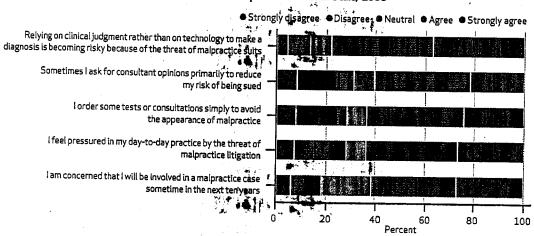
Practicing in a larger group was associated with greater malpractice concern. Physicians in practices with eleven to fifty doctors (with an average concern score of 68.8 points) expressed higher levels of concern than did physicians in solo or two-person practices (with an average concern score of 65.1 points). Group/ staff health maintenance organization (HMO) physicians had average concern scores of only 60.9 points. However, physicians in this kind of practice reported undertaking defensive medicine practices that were not significantly different from those used by any other group.

The proportion of patients with a chronic illness affected levels of malpractice concern. Physicians whose practices were predominantly (more than 50 percent) patients with chronic illnesses had average concern scores of 66.8 points, while physicians whose practices had relatively few such patients (less than 10 percent) reported average concern scores of 60.8 points.

The use of health information technology (IT) was not associated with significant differences in but it does not appear to be consistent. An in malpractice concern. This was true whether health IT use was determined by the use of an

EXHIBIT 1

Physicians' Level Of Agreement With Items In The Malpractice Concerns Scale, 2008



source Center for Studying Health System Change (HSC) Health Tracking Physician Survey, 2008.

EXHIBIT 2

Adjusted Percentage Of Items In The Malpractice Concerns Scale With Which Physicians Agreed Or Strongly Agreed, By Specialty, 2008

Specialty	% of physicians	Composite score ³	Defensive medicine subscore ^b	Malpractice concern
All physicians	s 100.0	65.4	62.0	67.7
Emergency physicians	5.8	82.0***	77.3****	83.3***
Obstetrician-gynecologists	6.6	77.2****	68.5	81.0***
Surgical specialists	21.3	71.4***	65.5	75.3***
Adult primary care physicians		1 July 1 1 2	1	
(reference group)	31.1	66.4	66.5	65.8
Pediatric specialists	2.1	59.6	50.8***	62.5
Adult cognitive specialists	10.3	59.0***	55.8***	61.7***
Adult procedural specialists	8.2	58.6***	51.5***	65.8
General pediatricians	7.6	57.4****	563***	56.3****
Psychiatrists (adult and pediatric)	6.9	51.4***	43.8***	54.2***
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source Center for Studying Health System Change (HSC) Health Tracking Physician Survey, 2008. NOTES Adjusted for physician's sex, years in practice, and practice type; number of physicians in practice; percentage of revenue from Medicare and from Medicaid; percentage of patients with chronic illnesses; and percentage of patients who are members of a racial or ethnic minority group. Percentage may not add to 100 percent because of rounding. 'Percentage of statements with which physicians agreed or strongly agreed. 'Percentage of statements related to defensive ordering of tests or consultations with which physicians agreed or strongly agreed. 'Percentage of statements related to overall concern regarding malpractice with which physicians agreed or strongly agreed. 'Percentage of statements related to overall concern regarding malpractice with which physicians agreed or strongly agreed. 'Cognitive specialists' primary role involves providing diagnostic or therapeutic advice to reduce clinical uncertainty or recommend a course of treatment. Procedural specialists' primary role involves performing a technical procedure to aid diagnosis, cure a condition, identify and prevent new conditions, or palliate symptoms. See Forrest C. A typology of specialists' clinical roles. Arch Interit Med. 2009;169(11):1062–8. **p < 0.05 ***p < 0.01

electronic medical record; the use of an electronic record with clinical decision support; or the use of an electronic record with automated reminders, e-prescribing, decision support, and other features. Variation in response patterns across the subscales was minimal.

STATE LIABILITY ENVIRONMENT We compared levels of malpractice concern in states with varying levels of medical liability, as represented by several different measures (Exhibit 4). Results that were not significant are not shown. Full results are in Appendix Exhibit 3.14

There is wide state-to-state variation in physicians' risk of incurring a malpractice claim—through either a settlement or a trial verdict—as well as the average size of paid claims. The average actual malpractice risk in the one-third of states with the highest valles (as defined by the number of paid claims multiplied by the size of the awards) is more than three times that found in the third of states with the lowest values—\$5,081 versus \$1,662 per physician. Average actual malpractice risk is defined as the rate of malpractice claims per 1,000 physicians that providers or their designees, must pay, multiplied by the average dollar amount of the award.

Although physicians' malpractice concern was positively and significantly associated with average malpractice risk, the relationship is fairly weak in light of the more than threefold differ-

ence in objective measures of risk. Physicians in the highest-risk states had survey composite scores only 4.3 percentage points higher than those practicing in the third of states with the lowest risk: 67.8 percent versus 63.5 percent (p < 0.01). These general trends also apply to the components of malpractice risk—the paid claims rate and average award size. However, only the comparison between the highest and lowest one-third is statistically significant.

The same pattern applies to malpractice insurance premiums. There is nearly a threefold difference between average specialty-adjusted malpractice premiums in the bottom and top thirds of states. Yet physician survey composite scores in the third of states with the highest premiums were 66.2 percent—just 5.4 percentage points higher than comparable scores in the third of states with the lowest premiums, where they were 60.8 percent (p < 0.01).

We examined the relationship of malpractice concern to several state tort reforms (Appendix Exhibit 1). Empirical research has demonstrated that a few reforms—most notably, caps on noneconomic damages—can affect liability insurance premiums and the use of services considered to be indicative of defensive medicine. Overall, physicians' malpractice concerns appear to be relatively insensitive to their states' malpractice reforms, including caps on noneco-

Adjusted Percentage Of Items In The Malpractice Concerns Scale With Which Physicians Agreed Or Strongly Agreed, By Physician And Practice Characteristics, 2008

Characteristic	Percent of physicians	Composite score
All physicians	100.0	65 A
Years in practice	And the second s	
Fewer than 5 (ref)	8.2	70.4
5–10	21.1	66.9
More than 10	70.7	64.4**
Sex		
Male (ref)	725	67.2
Female	27.4 22.4	60.7
Percent of patients with a chronic illness	2 E	A Miles and A Mile
<10% (ref)	9.9	60.8
10%-49%	. 28.4	64.1
≥50%	61.7	66.8***
Practice type/number of physicians		
::::::::::::::::::::::::::::::::::::::	320	65.1
3-10 physicians	24.2	674
i 11÷50 physicians	97	688*
≥51 physicians	61-24	676
Group/staff; HMO:	35. 7	60.9
	Control of the Contro	hatistatudus Ozast Madada kalistatudus kalentrilatudus kalistatudus kalistatudus k
	- 72	

SOURCE Center for Studying Health System Change (HSC) Health Tracking Physician Survey, 2008. NOTES Excluding the characteristic of interest, reported malpractice concern scores are adjusted for physician specialty, sex, and years in practice; practice type and number of physicians; percentage of revenue from Medicare and from Medicaid, percentage of patients who suffer from chronic disease; and percentage of patients who are members of racial or ethnic minority groups. This exhibit omits characteristics for which no significant differences were found at the 0.05 level. The omitted characteristics are percentage minority patients, use of health information technology with clinical decision support, routine use of full electronic medical record, and routine use of full electronic medical record with decision support. We also omitted urbanicity of practice location. We tested for differences between urban areas with a population of one million or more—the reference group—and urban areas with a population of less than one million and nonurban areas. The only difference we detected compared to the reference group was in nonurban areas ($\rho < 0.05$) on the malpractice concern score. Full results are available the Appendix Exhibit 2, which can be accessed by clicking on the Appendix link in the box to the right of the article online. Percentages, may not add to 100 percent because of rounding HMO is health maintenance organization. CHC is community health reports. Percentage of statements with which physicians agreed or strongly agreed. Defensive medicine and malpractice concern subscores are in Appendix Exhibits 2 and 3, available online as above. ** $\rho < 0.05$

nomic and punitive damages. Again, variation across subscales was minimal.

States that had established caps on total damages or abolished joint-and-several liability²² were associated with modestly lower levels of physician malpractice concern. Differences associated with other tort reforms, such as collateral-source rule reform and periodic payment reform, ²³ were not statistically significant. Two reforms, split recovery and patient compensation funds, ²⁴ were associated with significantly higher levels of concern.

Discussion

This study of a nationally representative sample of physicians found high levels of concern about the risk of malpractice litigation among physicians across a range of specialties, practice settings, and geographic areas. Physicians in specialties generally considered to be at highest

risk for costly malpractice claims, such as emergency medicine, expressed the greatest concern.

The relationship between physicians' level of mappractice concern and some objective measures of the riskiness of the state liability environment, such as malpractice premium levels and the risk of incurring a paid malpractice claim, was statistically significant. But the magnitude of these associations was very modest.

To put our results in perspective, the largest difference in physician concern across tertiles—or thirds—of malpractice risk was 5.4 points on a 100 point scale. This is roughly equivalent to the observed difference in concern between an average general surgeon and an average primary care provider, or one-third of the difference between the average emergency physician and the average primary care provider.

For other measures, such as the number of paid claims and the average amount paid per claim, physicians with twice the objective mea-

EXHIBIT 4

Physicians' Adjusted Agreement With Items In The Malpractice Concerns Scale, By Characteristics Of State Malpractice Environment, 2008

Independent variable	Value/category	Percent of physicians	Composite score
CLAIMS-BASED AND PREMIUM-BASED MEASURE	S OF MALPRACTICE RISK	• •	• 1
Number of paid malpractice claims per 1,000 physicians ^{a,c} Average payment per paid claim ^{a,c}	Bottom third (ref) (5.5) Top third (14.6) Bottom third (ref)	26.6 34.2	64.5 67.4**
Malpractice claim risk per physician	(\$203,431) Top third (\$467,290) Bottom third (ref)	32.2 37.4	64.5 66.9**
(claims rate times average award)	(1,661,786) Middle third (2,672,158) Top third (5,081,207)	45.6 14.5 39.9	63.5 64.6***
Malpractice premium ⁴ (annual)	Bottom third (ref) (\$24,026) Middle third (\$41,801)	14.6 38.2	67.8*** 60.8 65.1***
STATE-LEVEL TORT REFORMS ^{4,6}	Top third (\$70,227)	47.2	66.2***
Cap on punitive damages	No Yes	39.4 60.6	64.3 66.1
Caps on total damages	No Yes	91.9 8.1	65.7 61.7**
Split recovery	No Yes	88.2 11.8	64.9 68.8***
Patient compensation fund	No Yes	80.8 19.2	64.8 67.9***
Joint-and-several liability abolished	No Yes	24.3 75.7	67.4 64.7***

sources Center for Studying Health System Change (HSC) Health Tracking Physician Survey, 2008; National Practitioner Databank; 2009 Medical Liability Monitor Annual Rate Survey; Area Resource File, 2008; and Database of State Tort Law Reforms, 3rd edition.

NOTE Percentages may not add to 100 percent because of rounding. "Percentage of statements with which respondents agreed or strongly agreed. Defens Weredicine and malpractice concern subscores are available in Appendix Exhibits 2 and 3, available by clicking on the Appendix link in the box to the right of the article online. "Number of paid claims and average payment per paid claim were obtained from Statehealthfacts.org, which used the National Practitioner Databank to generate state-level estimates as of June 2009. These data include both trial verdicts and settlements. The cutoff points for the middle third for "Number of paid malpractice claims per 1,000 physicians" and "Average payment per paid claim" were 8.2 and \$302,035, respectively. Results for these categories were not significantly different from the reference groups at the 0.05 level and are omitted here. Full results are available in Appendix Exhibit 3, as in Note b. "Malpractice premiums were calculated by HSC as a weighted average of premiums reported by individual companies based on market share data from the National Association of Insurance Commissioners and premium data from the 2009 Medical Liability Monitor Annual Rate Survey. Regionally reported data were weighted by the number of physicians in the area from the 2008 Area Resource File. Weighted estimates did not differ greatly from unweighted estimates. "State reforms for which there were no statistically significant differences at the 0.05 level are not shown. Full results are in Appendix Exhibit 1, as in Note b. "Presence of various tort reforms: Database of State form. Law Reforms, 3rd edition. For definitions, see Appendix Exhibit 1, as in Note b. "Presence of various tort reforms: Database of State form."

sure of malpractice risk had levels of concern (as measured by concern scores) that were only 2.9 percent and 2.5 percent, respectively, higher than those of their peers at lower risk:

Malpractice concern was somewhat lower among physicians who practiced in states that had established caps on total damages or abolished joint-and-several liability. However, the presence of other types of tort reforms in the state, including caps on noneconomic damages, did not significantly reduce levels of physician concern, relative to states without such reforms.

MALPRACTICE AS 'DREAD RISK' The high level of malpractice concern among physicians in our

sample, even those practicing in relatively lowrisk environments, is striking.^{25,26} Although previous studies reflected conditions during a malpractice insurance "crisis" in 2001–5 marked by deteriorations in the availability and affordability of insurance, our results indicate high levels of concern even during a period of relative stability in malpractice insurance.

Our survey asked about the perceived threat of being sued rather than about difficulties securing insurance. But the two may be linked in many physicians' minds, particularly in states where underwriting practices changed during the crisis, making it harder for those who incurred a claim to renew their policies. Even considering these difficulties, however, the level of liability concern reported by physicians is arguably out of step with the actual risk of experiencing a malpractice claim.

It is possible that physicians lack access to accurate information about their absolute risk of being sued or their relative risk compared to their peers in other specialties or geographic areas. Advocacy efforts by medical professional societies in support of tort reform may contribute to this problem by conveying the impression that most or all states and specialties are in crisis and require additional legal protection.

A second possible explanation is that physicians exaggerate their concern about being sued, using it as a justification for high-spending behavior that is rewarded by fee-for-service payment systems. However, we found that levels of concern were fairly high even among physicians in staff-model HMOs, who have less financial incentive to overuse services. Moreover, some defensive medical practices, such as referring patients for consultations, do not generate reimbursement for the referring physician.

A third explanation relates to well-documented human tendencies to overestimate the risk of rare events and to be particularly fearful of risks that are unfamiliar, potentially catastrophic, or difficult to control. Lawsuits are rare events in a physician's career, but physicians tend to overestimate the likelihood of experiencing them. Surveys of the public demonstrate much higher levels of fear of dying in an airplane crash than in a car accident, even though the latter fate is far more likely. Severe, unpredictable, uncontrollable events are associated with a feeling of dread that triggers a statistically irrational level of risk aversion.

Physicians may be subject to this phenomenon when it comes to malpractice suits. Because of the rarity of suits, most physicians have little familiarity with them. The consequences of being sued are perceived as potentially disastrous to one's medical reputation, psychological well-being, and financial stability. Finally, physicians tend to view lawsuits as random events, unpredictable and uncontrollable, because they are not viewed as related to the quality of care provided.²⁹ These factors may lead to a fear of suits that seems out of proportion to the actual risk of being sued.²⁹

POLICY IMPLICATIONS Whether justified or not,

physicians' concerns about liability risk are a policy problem because defensive practices raise health care costs and may subject patients to unnecessary tests and procedures. Although many medical professional organizations continue to press for liability-limiting tort reforms, we found that many such reforms were not associated with a significant difference in physicians' malpractice concerns. In particular, the most strongly advocated reform, capping noneconomic damages, was not associated with a significant difference in perceived malpractice risk.

This finding is at odds with other research demonstrating that damages caps are associated with reduced defensive medicine, as measured by lower intensity of health service use.30 If the causal mechanism linking tort reforms and service use is physicians' perception that the reforms reduce their malpractice risk, one would expect a more robust relationship between these reforms and the perceived threat of malpractice in surveys such as ours. It is likely that physicians assessment of their risk is driven less by the true risk of malpractice claims or the cost of malpractice insurance, and more by the perceived arbitrary, unfair, and adversarial aspects of the malpractice tort process—which most traditional state reforms do not address.

Recently funded federal demonstration projects will test innovative approaches to liability reform, which may prove more helpful than traditional approaches. These experiments include alternatives to the usual civil litigation process by emphasizing early settlement of claims through less adversarial processes. Provisions in the new federal health reform law also may address aspects of the practice environment that contribute to defensive medicine. For example, reforms that promote bundled payments for health care services may create a financial incentive for providers to omit certain widely used tests and procedures of questionable usefulness.

Although alterations in reimbursement policy could prove a powerful lever for reducing overuse of care, the threat of lawsuits will remain a dread risk for physicians—and will undermine reimbursement reforms—until comprehensive liability reform is adopted. Reimbursement reform and liability reform therefore should be seen as complementary strategies—each indispensable—for reducing overuse of health services and encouraging physicians to adhere to recommendations for evidence-based care.

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authors and do not necessarily represent the views of the Department of Veterans Affairs.

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National Costs Of The Medical Liability System

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ABSTRACT Concerns about reducing the rate of growth of health expenditures have reignited interest in medical liability reforms and their potential to save money by reducing the practice of defensive medicine. It is not easy to estimate the costs of the medical liability system, however. This article identifies the various components of liability system costs, generates national estimates for each component, and discusses the level of evidence available to support the estimates. Overall annual medical liability system costs, including defensive medicine, are estimated to be \$55.6 billion in 2008 dollars, or 2.4 percent of total health care spending.

uring the push to pass federal health reform legislation, considerable attention focused on the possibility that medical liability reforms could "bend the health care cost curve."1-3 Conservatives in Congress and others argued that liability reform would address two drivers of health care costs: providers' need to offset rising malpractice insurance premiums by charging higher prices, and defensive medicine—clinicians' intentional overuse of health services to reduce their liability risk. President Barack Obama elevated the profile of liability reform by acknowledging that "defensive medicine may be contributing to unnecessary costs" and by authorizing demonstration projects to test reforms.4.5

Background

PREVIOUS ANALYSES Notwithstanding this interest in liability reform, rigorous estimates of the cost of the medical liability system are scarce. The most commonly cited figures are from a 2004 Congressional Budget Office (CBO) report that concluded, based on unspecified data provided by a private actuarial firm and the Centers for Medicare and Medicaid Services (CMS), that malpractice costs—excluding defensive medic; for physicians of being sued. Second, we did not cine—account for less than 2 percent of health

care spending.6

In a subsequent analysis, PriceWaterhouse-Coopers used the 2 percent figure, then extrapolated from estimates of the practice of defensive medicine in a study of care for two cardiac conditions by Dan Kessler and Mark McClellan.7 On that basis, the firm reported that the cost of insurance and defensive medicine combined account for approximately 10 percent of total health care costs. More recently, the CBO concluded that implementing a package of five malpractice reforms would reduce national health spending by about 0.5 percent9 but did not estimate total malpractice costs.

CURRENT ANALYSIS In this article we estimate the cost of the medical liability system in order to better understand its potential to affect overall health spending. We break down the various components of liability system costs, use the best available data to generate national annual estimates for each component, and discuss the quality of the evidence available to support these estimates.

▶ LIMITATIONS: Our analysis was limited in two key respects. First, we did not attempt to estimate social costs that cannot be readily expressed in monetary terms. For example, we did not include the reputational and emotional costs evaluate the social benefits of the medical liabilMichelle M. Mello (mmello@ hsph.harvard.edu) is a professor of law and public health at the Harvard School of Public Health, in Boston, Massachusetts.

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ity system, of which there are arguably at least three types.

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▶ SOCIAL BENEFITS OF THE LIABILITY SYSTEM: The system makes injured patients whole by providing compensation; it provides other forms of "corrective justice" for injured persons, which produces psychological benefits; and it reduces future injuries by signaling to health care providers that they will suffer sanctions if they practice negligently and cause injury.

However, it is not possible to quantify these benefits. Reliable evidence about the deterrent effect of the tort system does not exist. With respect to the benefits flowing from the tort system's compensation and corrective justice functions, not only is no evidence available, but it is not clear how to measure them. Although these benefits cannot be quantified, they certainly exist, and they should be considered in discussions of the social value of liability. The economic burden of preventable medical injuries is considerable, estimated to be \$17–\$29 billion per year, and improving patient safety is important whether or not the improvement is achieved in part through malpractice litigation.

▶ PURPOSE: Our purpose in this analysis was not to examine whether the medical liability system is worth maintaining, meaning whether its costs are justified by its benefits. Rather, we sought to understand the extent to which it contributes to health care spending.

Components Of Medical Liability System Costs

The total monetizable costs of the medical liability system—those that can be quantified and expressed in monetary terms—can be divided into several components (Exhibit 1). The major categories of costs are indemnity payments, or the amounts that malpractice defendants, typically through their liability insurers, pay out to patients who file malpractice claims against them; administrative expenses, consisting of attorneys' fees and other legal expenses for both sides, plus insurer overhead; defensive medicine costs, which are the costs of medical services ordered primarily for the purpose of minimizing the physician's liability risk; and other costs, some of which are difficult or impossible to quantify in economic terms. All costs are presented in 2008 dollars.

Notably missing from this list are malpractice insurance premiums. Premiums represent insurers' best estimates of their indemnity costs and defense costs, plus additional amounts to cover other operating expenses, reinsurance costs, and profits or surplus building. It would be double counting to include both malpractice premium costs and indemnity and administrative costs.

We took the approach of itemizing indemnity and administrative costs rather than reporting total premium costs for two reasons. Profits are not part of the costs of paying malpractice claims or operating the necessary administrative struc-

EXHIBIT 1

Component	Estimated cost (billions of 2008 dollars)	Quality of evidence supporting cost estimate
Economic damages Noneconomic damages	\$5.72 \$3.15 \$2.40 \$0.17	Good as to the total moderate as to the precision of the split among the components
Administrative expenses Plaintiff legal expenses Defendant legal expenses	\$4.13° ; \$2.00° ; \$4.109	Moderate Good
Other overhead expenses	\$3.04	Moderate Good
Defensive medicine costs Hospital services	\$45.59 \$38.79	Low
Physician/clinical services Other costs	\$6.80	ा निर्देश के कियो के विकास की सम्राप्त कर कर कर है।
Lost clinician work time	\$0.20	Moderate
Price effects	_b	Low
Reputational/emotional harm	h	No evidence

source Authors' analysis. Although plaintiff legal expenses are separately itemized, they are not included in the overall administrative costs total because, in the contingent fee system, they are already represented in the indemnity costs. These costs are not estimable with the available data.

tures to evaluate and pay claims. First, premiums include some additional costs that arguably should not be considered part of the costs of medical liability, such as insurer profit. Second, the available sources of premium data exclude many types of insurance entities, such as selfinsured hospitals, and therefore do not produce utterly reliable statistics.

Some cost components included in our analysis, such as awards for lost income in malpractice suits, represent a cost that would have been incurred by another party, such as the patient or a disability insurer, if the medical liability system had not covered it. In this sense, they are "transfer" costs, not additional costs.12 From a societal perspective, such components arguably should not be included in the analysis. However, policy, makers want to know how liability reform can be used to keep health care costs down. Thus, whether a patient's wages are paid by her employer or her doctor's liability insurance company matters a great deal.

Indemnity Payments

TOTAL INDEMNITY PAYMENTS There is no comprehensive, national repository of information; on medical malpractice claims.13 The source that comes closest is the National Practitioner Data Bank of the Health Resources and Services Administration (HRSA), but it has important limitations.

The data bank compiles information on all medical malpractice claims paid on behalf of health practitioners. Any entity that makes such a payment must report it to the data bank within ary 1, 2004, and December 31, 2008, the data bank received 63,370 reports.14 Excluding 1,923 duplicate reports, total indemnity payments reported over this period averaged \$4.24 billion per year.15

Although the data bank captures claims against physicians, it does not keep track of those against health care institutions such as hospitals and clinics. Institutions are often named as codefendants in claims brought against physicians; sometimes they are the sole defendants. Previous analyses of claims data from single states and insurers suggest that indemnity payments against institutions account for approximately 35 percent of total indemnity costs. Adjusting the data bank figure up accordingly (see the Online Appendix for more details about this process), 16 we estimated total national indemnity costs of approximately \$5.72 billion; for by noneconomic damages.20 per year (Exhibit 1).

INDEMNITY PAYMENT COMPONENTS There are three main types of damages in medical malprac-

tice cases and other tort litigation: compensatory damages for an injured plaintiff's economic losses, including past and future medical costs and lost wages; damages for noneconomic losses, also known as "pain and suffering"; and punitive damages, which are designed to punish defendants who have shown wanton disregard for the plaintiff's well-being.

Some courts are explicit in their verdicts for plaintiffs about how the indemnity dollars have been divided among the components, but many courts are not.17 More important, the vast majority of paid malpractice claims are settled out of court. The allocation between damages components in those settled cases is rarely explicit and is extremely difficult to track.

The best sources of information about the split among economic, noneconomic, and punitive damages in verdicts and out-of-court settlements combined are state databases of closed malpractice claims. Texas and Florida are among the few states that compile this information.18

For this study, we undertook a review of data on the composition of damages awards from those two states, together with an extrapolation to the national level that takes into account both the damages caps in Texas and Florida and the caseloads there relative to other states. This analysis suggests that a reasonable split to apply to a national indemnity total is approximately 55 percent economic damages, 42 percent noneconomic damages, and 3 percent punitive damages (see the Online Appendix).16 Exhibit 1 shows the cost figures that result from applying this split to the total indemnity estimate.

An important caveat to this estimate of the thirty days or risk civil penalties. Between Janua damages components is that applying its percentages to a national indemnity total masks tremendous variation at the case and state levels. In certain types of cases, noneconomic damages will account for virtually all of the award. Examples are cases involving plaintiffs with low or no income, such as the elderly, and injuries that result in little lost work time or medical expenses (for example, when the only injury is one or more scars, as opposed to something worse).19

Conversely, payouts designed to cover expensive care over extended periods tend to have very large economic components that dwarf the noneconomic components. Birth-related neurological injuries are the best example.19 At the state level, whether the jurisdiction has a cap on noneconomic damages—as half of the states currently do-and the level of that cap will heavily influence the proportion of the award accounted

Administrative Expenses

PLAINTIFF ATTORNEY FEES AND EXPENSES Attorneys' contingency fee levels reported in the literature for medical malpractice and other types of tort litigation converge fairly consistently in the range of 35–40 percent of awards to plaintiffs. ²¹ Because these costs are drawn from the case payouts, however, they should not be tallied separately from indemnity costs in calculating total system costs. To do so would be double counting.

Our recent study of 1,452 malpractice claims from five insurers in several regions found that defense costs averaged nineteen cents for every indemnity dollar paid out.²¹

OTHER OVERHEAD EXPENSES Malpractice insurers incur administrative expenses that are not directly related to defending claims. These include general operating expenses; commissions and brokerage expenses; and taxes, licenses, and fees. The A.M. Best Company reported that these costs totaled \$1.8 billion in 2008.²²

A.M. Best's figure does not include expenses of entities not subject to state insurance reporting requirements, including self-insured organizations. The market share of these organizations is not known, but to account for them, we increased the A.M. Best figure for other overhead costs by 10 percent, to \$1.98 billion (Exhibit 1).

Also relevant are the expenses of hospitals and other health care facilities on risk management offices that work to reduce and respond to medical injuries. These offices typically pursue activities aimed specifically at minimizing and managing claims, while also engaging in wider efforts to improve the quality and safety of care.

Because some quality improvement activities would take place even in the absence of tort liability, their total costs should not be charged to the liability system. However, there is little doubt that liability risk has led to much greater institutional investment in risk management.

The variety of institutional arrangements for risk-management functions imakes it challenging to estimate operational costs. Confidential budget figures that we obtained from hospital systems collectively representing 179 hospitals ranged from \$185,000 to \$1.9 million per hospital per year in 2008, with the latter figure being a self-described outlier.

Using the most conservative estimate of \$185,000, the estimated flational cost of risk-management operations for all 5,708 registered U.S. hospitals is approximately \$1.06 billion. This figure is also conservative because it does not include risk-management costs for other types of facilities, such as independent ambulatory surgery centers.

Defensive Medicine Costs

Although most scholars of malpractice agree that defensive medicine is highly prevalent, reliable estimates of its cost are notoriously difficult to obtain.²⁴ An initial challenge is to settle on a definition of *defensive medicine*.

The most commonly used definition, proposed by the now-defunct U.S. Congress Office of Technology Assessment (OTA), conceptualizes defensive medicine as occurring "when doctors order tests, procedures, or visits, or avoid certain high-risk patients or procedures, primarily (but not solely) because of concern about malpractice liability."²⁴ This definition says nothing about the benefits—potentially substantial—to patients that may arise from greater use of medical services²⁵—or, for that matter, about the damages that patients could incur from excess or unnecessary care.

In contrast, definitions in the law and economics literature limit defensive medicine to spending that exceeds the socially optimal amount. Because our analysis focused on the costs of the liability system, rather than its benefits, we adopted the OTA definition. It is important to note, however, that our calculations ignored benefits arising from this spending.

Even with this definition, considerable uncertainty surrounds estimates of defensive medicine costs. Previous research has examined the use of a small set of specific procedures, surveyed physicians about "consciously defensive" medicine, or compared the intensity with which specific cardiac conditions are treated in states with and without tort reforms.^{7,24,26-28}

Extrapolation from a handful of procedures or conditions to a national estimate is problematic, and physician survey reports may overstate or understate the true prevalence of defensive practices. Studies comparing states with and without tort reforms calculate only the change in the amount of defensive medicine associated with an increase in liability exposure, not the absolute magnitude of defensive medicine costs.

There are also difficulties in adequately controlling for variations in practice styles across geographic areas arising from factors other than liability pressures. Finally, most studies were conducted prior to the mid-1990s, and the magnitude of their estimates might not apply today.

HOSPITAL SERVICES To produce the most rigorous possible estimate of the magnitude of defensive medicine, in spite of these limitations, we began with a finding from the most widely cited academic paper on this topic. Kessler and McClellan examined the effect of tort reforms that directly reduce expected malpractice awards—such as caps on noneconomic damages—on Medicare hospital spending for acute

Considerable uncertainty surrounds estimates of defensive medicine costs.

myocardial infarction and ischemic heart disease from 1984 to 1990.⁷ The reforms lowered hospital spending by 5.3 percent for myocardial infarction and 9.0 percent for heart disease.

In subsequent work examining data through 1994, Kessler and McClellan found that such direct reforms reduced hospital spending by 8.3 percent, but this estimate was based only on data about myocardial infarction.²⁹ In a further analysis incorporating information about levels of managed care through 1994, they estimated that direct reforms reduced hospital spending by 3.8 percent for myocardial infarction and 7.1 percent for heart disease.³⁰

Two other studies could not replicate these findings for other health conditions. ^{6,31} Consequently, national extrapolations from Kessler and McClellan's estimates should be interpreted with considerable caution. Treatment intensity for other diagnoses may be less subject to physician discretion than cardiac care. Nevertheless, Kessler and McClellan's studies remain the best available basis for estimating national costs.

In our analysis, we used a value of 5.4 percent for the effects of defensive medicine on hospital spending, a conservative assumption that represents the lower of Kessler and McClellan's original estimates and the midpoint between their latest estimates. National health spending for 2008 was estimated to have been \$2.3 trillion, of which \$718.4 billion was hospital spending.³² Our 5.4 percent estimate suggests that \$38.8 billion of this spending could be reduced through direct tort reforms.

This estimate understates the magnitude of defensive medicine under two conditions: first, if the passage of direct tort reforms reduces only a portion of defensive medicine, as we believe it does; and second, if physicians perceive that elderly Americans—recall that Kessler and McClellan's estimates come from a Medicare population—are less likely than other patients to sue or, if they sue, to recover large awards.

However, the estimate overstates the magnitude of defensive medicine if physician re-

sponses to liability in the realm of cardiac care are more dramatic than in other clinical areas, or if responses are larger for Medicare patients than for privately insured patients. The latter might be the case because higher levels of managed care outside of Medicare reduce physicians' discretion.

Balancing these competing sources of bias is difficult, but the two sets of concerns probably serve as counterweights to one another.

physician and clinical services The above cost estimate relates solely to hospital spending, but defensive medicine also occurs in other settings. Our prior work found that between 1993 and 2001, malpractice payments per physician grew by 11 percent and were associated with a 1.1 percent increase in Medicare reimbursement for all physician and professional services in Medicare Part B. Similar results were obtained when malpractice premiums were used as a measure of liability. 33,34

We could use these figures to estimate the level of current annual spending that can be attributed to malpractice premium growth. A first step was to estimate the increase in Part B spending that may be attributed to malpractice liability between 1993 and 2001. The total is \$2.9 billion, or 11 percent of Part B spending in 1993.

However, this calculation ignored the role of malpractice payments made on behalf of physicians before and after that period in contributing to the current level of spending. We estimated the increase in defensive medicine since 2001 by making two assumptions.

First, we assumed that the association between malpractice payments and health spending is the same in the period after 2001 as it was in the 1993-2001 period. That is, we assumed that an 11 percent average annual growth in malpractice payments was associated with 1.1 percent average annual growth in reimbursements. Second, we assumed that malpractice payments grew at the same average annual rate after 2001 that they did in 1993-2001.

With these assumptions, we estimated that a total of \$2.5 billion in physician and clinical spending since 2001 was attributable to defensive medicine. Adding this amount to the \$2.9 billion spent in the 1993–2001 period resulted in a total of \$5.4 billion for the cost of defensive medicine in the area of physician and clinical services since 1993.

As noted earlier, this calculation still ignored the contribution of defensive medicine to the absolute level of health care spending in 1993. This is an extremely difficult parameter to estimate (see the Online Appendix). We can provide only a rough estimate.

In 1960, spending on physician and clinical

services was \$39.3 billion in 2008 dollars. Assuming that malpractice payments per physician grew at an average annual rate of 1.3 percent, we would expect spending on this class of services to be \$2.8 billion more in 2008. Thus, our estimate range for the cost of defensive medicine in 2008 for physician and clinical services is \$5.4-\$8.2 billion. This midpoint of this range is \$6.8 billion.

OVERALL ESTIMATE Combining the amounts for hospital and physician spending, we arrived at an overall estimate of \$45.6 billion in defensive medicine costs for 2008. Although our figure was based on methodologically strong studies, because the hospital spending estimates were derived from a narrow range of diagnoses, the quality of evidence supporting our systemwide estimate is best characterized as low.

Other Costs

There are a number of other, indirect costs of the medical liability system, most of which are not possible to estimate.

suits against physicians produce costs of time away from patient care for legal proceedings, with resulting lost productivity and income. The median amount of work time that being sued costs a physician is in the range of 2.7–5 days, according to two surveys of malpractice defendants. Given an estimated 50,000 new malpractice claims against physicians annually and an average 2008 physician income of \$272,000, we estimated that the total value of lost work days is \$140-\$260 million (see the Online Appendix). Our systemwide cost estimate is at the midpoint of this range, \$200 million.

dicate that physicians in group practices preserve their net income in the face of malpractice premium increases by increasing both the volume of services they perform and the unit prices they charge. They also takes the form of higher volume; pice effects are comparatively modest.

It is impossible to determine how much of the increase in volume constitutes defensive medicine—services performed primarily to reduce liability risk—as opposed to services performed primarily to enhance revenue. Price may also be affected by a reduced supply of medical services. If rising malpractice premiums lead some clinicians to leave practice or reduce the range of services they offer; the remaining providers may be able to charge higher prices.

Such effects are, however, largely theoretical

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Reforms that offer the prospect of reducing these costs have modest potential to exert downward pressure on overall health spending.

at this point. We did not include effects on prices in our estimates because we were unable to quantify them reliably, and because it would result in double counting to the extent that they are already included in the hospital and outpatient spending outlined above.

REPUTATIONAL AND EMOTIONAL TOLL ON CLINICIANS Physicians can insure against malpractice awards by purchasing insurance, but they cannot insure against the psychological costs of being involved in litigation, including the stress and emotional toll. Nor can they avoid the reputational effects of being sued, which affect their income as well as their status. Whether or not they prevail in a lawsuit, physicians anecdotally report that these effects occur.³⁹

Few studies have attempted to estimate the extent of these harms, ⁴⁰ and none has quantified the resulting financial losses. To the extent that patients take their business elsewhere, reputational costs represent a transfer from one physician to another. Emotional costs do not. They are not likely to confer any social benefit, because there is no evidence that this stress and anxiety improve the quality of care. Although impossible to quantify, and therefore not included in our estimates, these costs may be large.

Overall System Cost Estimates

Combining the various cost components, we estimated the total annual cost of the medical liability system to be \$55.6 billion in 2008 dollars (Exhibit 1). This amount is equivalent to approximately 2.4 percent of total national health care spending in 2008.

We have highlighted the many limitations to the data available to support this analysis. Our estimates should be interpreted cautiously, with recognition that some system cost elements were excluded and others—particularly the defensive medicine figures—were estimated based on substantial assumptions and extrapolations.

Exhibit 1 summarizes the quality of the evidence underlying each of the component estimates. Although our estimates are imperfect, they are more comprehensive, transparent, and firmly grounded in the best available data than previous estimates of liability system costs.

Conclusion

The medical liability system costs the nation more than \$55 billion annually. This is less than some imaginative estimates put forward in the health reform debate, and it represents a small fraction of total health care spending. Yet in absolute dollars, the amount is not trivial.

Moreover, to the extent that some of these costs stem from meritless malpractice litigation, they are particularly objectionable to health care providers. The psychological and political value of addressing this grievance could be considerable.

Reforms that offer the prospect of reducing these costs have modest potential to exert down-

ward pressure on overall health spending. Reforms to the health care delivery system, such as alterations to the fee-for-service reimbursement system and the incentives it provides for overuse, probably provide greater opportunities for savings.

Some aspects of federal health reform may reduce medical liability costs. Extending health insurance coverage to the uninsured may reduce their need to file malpractice claims to recoup medical expenses occasioned by injuries caused by malpractice.

Additionally, in states that have adopted "collateral source offsets"—meaning that costs covered by health insurance cannot be recovered by malpractice plaintiffs—greater prevalence of health insurance will mean more frequent offsets, lower total indemnity payments, and less "double payment" of medical expenses. A farther-reaching reform that merits discussion would be to impose a federal collateral-source offset in connection with the move to universal coverage. In these respects, health reform and liability reform may have unexpected synergies in bending our cost curve down.

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Gawande was an adviser to Bill Clinton during his 1992 decirition presidential campaign and subsequently directed three committees of the Clinton health reform task force. He is the author of a number of New Yorker pieces, including a June 2009 essay titled "The Cost Conundrum," which President Barak Obama cited during Congress's deliberations on health care reform. In 2006 Gawande was named a MacArthur Fellow.



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In 2004 Studdert received the Alice S. Hersh New Investigator Award. The author of more than a 120 articles and book chapters. Studdert is currently examining compensation system reform, informed consent, disclosure of medical injury, and the work of coroners in Australia.

According to Mello, it was sheer fatigue that drove this stellar cast, of authors to focus their efforts on addressing the question of how much medical liability contributes to overall U.S. health care costs. Mello explained that she and her coauthors were "getting the same questions from reporters and congressional staff over and over. How much does malpractice litigation really cost, and how much would federal tort reform bend the health care cost curve down?"

Mello noted that they were "hearing some very imaginative estimates." She and her colleagues concluded that a "more defensible estimate would contribute to the policy debate about liability reform" by bringing to bear the best available evidence.

Mello and Studdert have collaborated in the past on estimating national costs of malpractice litigation. However, this effort represents the first tim that all four of these authors have worked together. Mello noted that Chandra was brought on board "as an expert on the defensive medicine side," while Gawande' involvement was to help ensure that the authors kept in mind the "big picture," including "what other aspects of health reform might contribute to cost control. and how health reform and liability reform might interact."

In the end, Mello said, the medical malpractice cost estimate the authors derived "was not out of step with [their] expectations," given their belief in the soundness of the dominant defensive medicine cost component, which they knew would "drive the total figure pretty heavily." Mello added that her next step, along with Studdert, will be to estimate the cost of a "health court" system that could replace traditional tort litigation for medical malpractice.

